

CHAPTER 4

ESCALATED ENFORCEMENT ACTIONS

Chapter 4 provides guidance regarding:

- ▶ the use of caucuses, panels, and conferences in the enforcement process
- ▶ escalated enforcement actions that can be taken
- ▶ the criteria to be used to determine whether a civil penalty should be proposed
- ▶ settlement of enforcement proceedings and actions

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4.1 Predecisional Enforcement Conferences and Regulatory Conferences

- a. **Predecisional Enforcement Conferences (PECs)** are normally open meetings between the NRC and a licensee, vendor, or other person when the NRC has learned of apparent violations for which escalated enforcement action appears warranted.
- b. **Regulatory Conferences** are normally open meetings between the NRC and reactor licensees to discuss issues that the SDP assessment determines to be potentially risk significant (i.e., red, yellow, or white), whether or not violations are involved.
 1. Because the significance assessment from the SDP determines whether or not escalated enforcement action will be issued (i.e., a Notice of Violation (NOV) associated with a red, yellow, or white SDP finding), a subsequent predecisional enforcement conference is not usually necessary.

2. Although regulatory conferences are similar to predecisional enforcement conferences in many respects, specific guidance for regulatory conferences is included in [NRC Inspection Manual Chapter \(MC\) 0609](#).
- c. The decision to hold a PEC or a Regulatory Conference with enforcement implications does not mean the agency has concluded that a violation has occurred or that enforcement action will be taken.
- d. The purpose of the conference is to obtain information that will assist the NRC in determining the appropriate enforcement action, e.g.:
1. A common understanding of the facts, root causes, and missed opportunities to identify the violation sooner;
 2. A common understanding of corrective actions; and
 3. A common understanding of the significance of the issues and the need for lasting and effective corrective action.
- e. These conferences are not held to negotiate sanctions.

✓ Meeting notices for regulatory conferences with enforcement implications should be sent to “OEMAIL” and the OE Web site Coordinator “OEWEB” to ensure that these conferences are posted on the **Enforcement** Web site.

☞ PECs and regulatory conferences are normally categorized as Category 1 meetings in accordance with the Commission’s Public Meeting Policy. The policy statement as well as additional guidance on conducting public meetings is included on the [Communications and Public Meetings Web Site](#).

4.1.1 Applicability

- a. PECs and Regulatory Conferences will normally be held:
1. When the NRC needs additional information prior to making an enforcement decision involving a potential escalated action, i.e., Severity Level I, II, and III violations; violations associated with a red, yellow or white finding, civil penalties, and orders;
 2. Before issuing an order based on a violation of the Deliberate Misconduct rule;
 3. Before issuing a civil penalty to an unlicensed individual;
 4. To provide a licensee (or individual) an opportunity to discuss its perspective regarding the issues, prior to the NRC making enforcement decisions; and
 5. When the NRC needs additional information prior to making an enforcement decision involving a significant vendor case, such as those involving recurring nonconformances.

- b. The NRC may take immediate enforcement action, and hold the conference subsequently when:
1. If necessary to protect the public health and safety or provide for the common defense and security.
 2. In special cases where a PEC would not serve the agency's interest, e.g., where NRC is taking its action before DOJ has completed its activities addressing escalated criminal issues.
- c. A licensee, vendor, or other person may seek to waive their opportunity to participate in a conference.
1. The region should notify OE if a licensee seeks to waive a conference.
 2. If a licensee waives its opportunity to participate in a conference, a DFI may be warranted if the NRC needs additional information to make an enforcement decision.
- d. The region should consult with OE for those cases involving potential escalated enforcement action:
1. When the region proposes not to conduct a PEC if there has been an escalated enforcement action within the last two years or two inspections;
 2. If the violation is categorized at Severity Level I or II; or
 3. If the violation is willful.
- e. If the NRC concludes during an enforcement panel that a PEC is not necessary, the region may either:
1. Issue the inspection report including the apparent violations and providing the licensee a choice of requesting a conference or providing a written response to the apparent violations (“**a choice letter**”); or
 2. Make a telephone call to the licensee informing them that the NRC does not see the need for a conference and does not see the need for a civil penalty (“**choice call**”).
- ☛ Issuing a choice letter may be appropriate where a licensee appears to understand the significance of the violation and the need for corrective action at the inspection exit, but where the inspector may not be aware of all of the corrective actions subsequent to the inspection exit. Issuing a choice letter may provide the emphasis to the licensee to develop and implement comprehensive corrective actions to avoid the potential for a civil penalty.
- f. Notwithstanding the NRC's conclusion that a PEC is not necessary, a conference will normally be held if the licensee requests it.

4.1.2 Attendance at PECs and Regulatory Conferences

This section provides specific guidance concerning attendance at PECs and Regulatory Conferences, including: NRC personnel, licensee personnel, media and members of the public, and State government personnel.

4.1.2.1 NRC Attendance at PECs and Regulatory Conferences

a. NRC personnel should attend conferences according to the following guidelines:

1. The Regional Administrator should determine regional staff attendance at conferences.

☞ There should be a reason for each NRC person's attendance at PECs and Regulatory Conferences.

2. The region should be sensitive to the potential impact on a conference when the number of NRC attendees is significantly greater than the number of licensee attendees.

b. The region should discuss with the cognizant OE Enforcement Specialist or the Chief, Enforcement Policy and Program Oversight Section (EPPO), whether the issues to be discussed warrant OE attendance at the conference.

1. OE staff should attend all significant conferences, either in person or by video or telephone. (OE should generally not participate by telephone if safeguards information will be discussed.)

✓ If OE plans to participate in a conference in person or by video or telephone, the region shall send to OE, along with the inspection report, any additional relevant information, at least 72 hours prior to the conference.

2. If the Regional Administrator believes that telephone or video participation would make a particular conference less effective, OE should be notified at least one week in advance so that travel arrangements can be made.

c. The NRR, NMSS, or NSIR Enforcement Coordinator should attend conferences as deemed appropriate by the program office, or as requested by the region.

d. Additional program office designees (NRR/NMSS/NSIR technical or projects staff) may attend conferences as deemed appropriate by the program office, or as requested.

e. Regional Counsel should attend PECs, unless their schedule does not permit, and in particular, should attend those conferences involving complex or novel issues or those involving a complex or significant OI investigation.

f. OGC should be requested to attend conferences involving disputes over legal issues.

- g. OI should be invited to attend those conferences that involve a complex or significant OI investigation, or those that could potentially result in an OI referral for investigation.

4.1.2.2 Licensee Attendance at PECs and Regulatory Conferences

Licensee personnel should attend conferences according to the following guidelines:

- a. The region should request that licensee attendance include:
 - 1. Senior level managers and individuals prepared to address the circumstances of the apparent violations and the corrective actions, e.g., the Radiation Safety Officer; and
 - 2. A licensee senior representative empowered to bind the licensee to commit to corrective actions on its behalf.
- b. When an individual's significant personal error contributed to the violation, consideration should be given to that person's attendance at the licensee's conference because it may be beneficial for NRC management to hear first-hand the individual's explanation for the actions taken, to get a more complete understanding of the violation circumstances.
- c. When an enforcement action against an individual is contemplated, the opportunity should normally be provided for a specific conference with the individual.

4.1.2.3 Public Attendance at PECs and Regulatory Conferences

- a. PECs and Regulatory Conferences are generally:
 - 1. Classified as Category 1 meetings in accordance with the Commission Public Meeting Policy;
 - 2. Between the NRC and the licensee;
 - 3. Normally held in the regional office; and
 - 4. Open to public observation.
- b. Conferences will not normally be open to the public if the enforcement action being contemplated:
 - 1. Would be taken against an individual, or if the action, though not taken against an individual, turns on whether an individual has committed a wrongdoing;
 - 2. Involves significant personnel failures where the NRC has requested that the individual(s) involved be present at the conference;
 - 3. Is based on the findings of an NRC Office of Investigations (OI) report that has not been publicly disclosed; or

4. Involves Safeguards Information, Safeguards Information-Modified Handling (SGI-M), Privacy Act information, or information which could be considered sensitive or proprietary; and
 5. Involves medical misadministrations or overexposures and the conference cannot be conducted without disclosing personally identifying information about the individual involved, e.g., their name, employee number, etc.
- c. Conferences will not normally be open to the public if the conference will be conducted at a relatively small licensee's facility.
- d. Notwithstanding these criteria, a conference may still be open if:
1. The conference involves issues related to an ongoing adjudicatory proceeding with one or more interveners; or
 2. The evidentiary basis for the conference is a matter of a public record, such as an adjudicatory decision by DOL.
- ☞ Notwithstanding the criteria for opening or closing a conference to the public, with the approval of the DEDO, conferences may either be open or closed after balancing the benefit of the public observation against the potential impact on the agency's decision-making process in a particular case.
- e. The Regional Administrator has the discretion to determine whether the public should be allowed to observe a video conference on a case-by-case basis.
- f. The public attending an open conference may observe but not participate in the conference.
1. Members of the public may tape records (including videotape) an open conference if that activity is not disruptive.
 2. It is noted that the purpose of conducting conferences in the open is not to maximize public attendance, but rather to provide the public with opportunities to be informed of NRC activities while balancing the need for the NRC staff to exercise its regulatory and safety responsibilities without an undue administrative burden.
 3. Following the conference, the staff is to be available for a brief period to entertain questions and comments from members of the public concerning matters discussed at the conference.

4.1.2.4 State Government Attendance at PECs and Regulatory Conferences

- a. Since most PECs and Regulatory Conferences are open to the public, state government personnel will be able to attend.

1. If the particular conference is closed, the Commission's "[Policy on Cooperation with States at Commercial Nuclear Power Plants and Other Nuclear Production or Utilization Facilities](#)," dated February 15, 1989, and amended for adjacent states on February 25, 1992, permits State representatives to attend conferences if information relevant to an enforcement action is obtained by a State representative during an inspection under a State/NRC inspection agreement.
2. When other circumstances warrant, the Director, OE, may authorize the Regional Administrator to permit State personnel to attend a closed PEC or Regulatory Conference.
 - (a) Examples of situations where permission would be granted include where the State representative could provide helpful information or insight (e.g., the enforcement action involves a matter in which the State may also have a related regulatory interest or where the enforcement action involves a general license under 10 CFR Part 150 and an Agreement State has issued a specific license.
 - (b) If attendance by State personnel to a closed PEC has been deemed appropriate, the following guidelines should be met for closed conferences:
 - (1) State attendance should be from the appropriate State office (e.g., a person from the State office of operational or radiation protection safety and not from the State rate-setting office).
 - (2) The State attendee should be informed that participation during the conference is not allowed unless the State attendee was a participant in the inspection under discussion and, in that case, the State attendee may only make statements related to the areas inspected.
 - (3) If actual safeguards information is to be discussed, State personnel shall be excluded **unless** they have the necessary clearance.
 - (4) The State attendee must agree not to disclose the conference details with the media or the public documented in a non-disclosure arrangement between the state and NRC. Such agreement should be included in a Memorandum of Understanding (MOU) or, in its absence, a protocol agreement.
 - (5) This MOU or protocol agreement should be signed by the Regional Administrator, or his designee, and the State attendee or State liaison officer.
 - (c) The following is a sample protocol agreement:

“(State) will conform to NRC practices regarding information disclosure.
(State) will abide by NRC protocol not to disclose publicly inspection findings prior to official release of NRC inspection results. To preclude the premature public release of sensitive information (i.e., concerning matters under

investigation and security (safeguards) information), NRC and (State) will protect sensitive information to the extent permitted by the Federal Freedom of Information Act, 10 CFR 2.390, and other applicable authority. (State) will consult with NRC before releasing sensitive information to ensure that its release is not premature or would not affect an ongoing investigation or other NRC action. NRC will inform (State) of the release of sensitive information as appropriate. Additionally, neither NRC nor (State) will release proprietary data until a release is approved by the person(s) having proprietary rights therein or until release is approved by appropriate NRC management.”

3. Generally, only NRC personnel may attend enforcement caucus meetings following the conference.
 - (a) The Director, OE, may give prior approval for someone other than NRC personnel to be present at an enforcement caucus meeting.
 - (b) When the Director, OE, allows a person to attend a caucus, this person should sign a non-disclosure agreement prior to attending the caucus.

4.1.3 Scheduling and Announcing PECs and Regulatory Conferences

a. Whether a PEC should be conducted is determined during an enforcement panel. The process for determining whether to conduct a regulatory conference is governed by MC 0609, Attachment 1.

1. The region should issue the inspection report within four weeks of when the enforcement panel or SERP was conducted.
2. OE will have already assigned an EA number to the case.
3. Conferences should generally be held within 6 weeks after completion of an inspection. If a conference is scheduled subsequent to a licensee's response to a choice letter, the conference should generally be held within four weeks of receipt of the licensee's response.

☛ See Chapter 6 for additional guidance on cases involving individuals or cases that have been referred to the Department of Justice (DOJ). These cases require coordination with DOJ and approval of the Director, OE, prior to scheduling a PEC.

- b. The region should conduct a final exit briefing to inform the licensee:
1. That the NRC's would like to conduct a PEC prior to making an enforcement decision;
 2. Whether the conference will be open or closed to public observation;
 3. For closed PECs, if the PEC will be transcribed;

4. The purpose of the conference and the information that the licensee is encouraged to present at the conference.
 - (a) This will help direct the licensee's focus and ensure that the licensee understands what is expected at the conference.
 - (b) This communication is especially important for material licensees because of their infrequent contact with the NRC. If time permits, a written outline or agenda of specific issues should be provided; and
 5. That the licensee should begin its reviews based on the exit briefings, i.e., the licensee should not wait until the inspection report has been issued.
- c. The region should inform the licensee that any information provided during the conference, including handouts or preliminary evaluations, will be made available to the Public, unless it meets the provisions of 10 CFR 2.390(a)(4) or (a)(6).
 - d. The region should coordinate a date to hold the PEC with the licensee, with the goal of giving the licensee at least two weeks to review the inspection report.
 1. Licensees should have adequate time to perform necessary reviews or investigations, develop corrective action plans, and prepare presentations.
 2. Licensees are expected to base their presentation on the inspection exit meeting.
 - (a) The specific findings or issues of concern may not be fully understood until the licensee has received the written report.
 - (b) Unless prior approval is given by the Director, OE, or unless the licensee waives receipt of the inspection report, the licensee should normally be given the inspection report at least two weeks in advance.
- ✓ Inspection reports should be sent to OE and the appropriate program office at the same time the region sends it to the licensee.
- e. In addition to the inspection report, the licensee should normally be sent a factual summary for cases involving OI reports.
 - f. Additional time may be needed to prepare for conferences involving complex issues.
 1. The timeliness of the process is dependent on effective exit meetings.
 2. If, after the exit meeting, the agency concludes that different issues should be the focus of the conference:
 - (a) The licensee should be put on notice.

- (b) This should also be considered in scheduling the conference.
3. After the conference date and time have been set, the region should:
- (a) Promptly notify OE, the appropriate program office, OI (if applicable) and the appropriate State liaison officers (unless the conference is closed); and
- (b) Highlight any novel or complex cases for the attention of the Director, OE.
- g. The region should prepare a meeting notice in accordance with regional procedures and include information (as applicable) in the [Public Meeting Checklist Web Site](#). Meeting notices should also include specific enforcement-related information. Appendix D includes a checklist that consolidates the required information for conferences.
- h. The meeting notice should:
1. Include the EA number.
 2. Clearly identify the meeting as a "predecisional enforcement conference" or "regulatory conference."
 3. In the purpose statement, provide sufficient detail to inform the public about the general issues, including the activity area, or equipment involved.
 4. Refer to the issues as "apparent violations" or "potential noncompliances," to reflect the predecisional nature.
 5. Indicate whether the conference is open or closed to public observation.
 - (a) If the conference is open, include the following statement:

☛ The following examples demonstrate inadequate and adequate purpose statements for meeting notices:

NO The purpose of the meeting is to discuss the procedural violation identified in NRC Inspection Report No. 50-277/02-06.

YES The purpose of the predecisional enforcement conference is to discuss the apparent procedural violation involving the motor driven emergency feedwater pump.

NO The purpose of the predecisional enforcement conference is to discuss the deliberate transfer of licensed byproduct material without a specific license.

YES The purpose of the predecisional enforcement conference is to discuss the apparent willful violation involving the transfer of licensed byproduct material (EXIT signs containing tritium) without a specific license.

✓ If the case involves potential willfulness, the notice should refer to the issues generally as "apparent willful violations," instead of "apparent deliberate violations."

“This is a Category 1 Meeting: The public is invited to observe this meeting and will have one or more opportunities to communicate with the NRC after the business portion, but before the meeting is adjourned.”

(b) If the conference is closed, include one of the following statements:

“This conference is closed to public observation because it involves the findings of an NRC Office of Investigations report that has not been publically disclosed.”

or

“This conference is closed to public observation because it involves safeguards information, Privacy Act information, or information which could be considered sensitive or proprietary.”

or

“This conference is closed to public observation because it involves potential wrongdoing by an individual.”

or

“This conference is closed to public observation because it involves significant personnel failures where the NRC has requested that the individual(s) involved be present at the conference.”

or

“This conference is closed to public observation because it involves medical misadministrations or overexposures and the conference cannot be conducted without disclosing personally identifying information about the individual(s) involved.”

or

“This conference is closed to public observation because it will be conducted at a relatively small licensee's facility (or will be conducted by telephone).”

6. Include the inspection report number and the ADAMS accession number, if it is available.
 - i. The region should submit meeting notices for all conferences (open or closed) at least 10 calendar days in advance of the meeting to the Public Meeting Notice System Coordinator (e-mail “PMNS”).

<p>✓ Meeting notices for Regulatory Conferences with enforcement implications should include a statement that the meeting will also address whether enforcement action is warranted.</p>

- j. To support posting a conference to the [Enforcement Web site](#), the region should send a copy of the meeting notice (including the EA number) at the same time it sends the notice to the Public Meeting Notice System Coordinator, to:
1. "OEMAIL"; and
 2. The OE Web site Coordinator ("OEWEB").
- k. The region should notify OPA of all PECs and Regulatory Conferences.
1. OPA will determine whether to issue a press release announcing the conference.
 2. All press releases should include language that conveys:
 - (a) The decision to hold a predecisional enforcement conference does not mean that the agency has concluded that a violation has occurred or that enforcement action will be taken.
 - (b) Apparent violations discussed at predecisional enforcement conferences are subject to further review and may be subject to change prior to any resulting enforcement action.
 - (c) The conference is an opportunity for the licensee to present any additional material information before the NRC arrives at a decision.
- l. The only exception to issuing a meeting notice may be when security-related issues are involved.

✓ It is very important in meeting the intent of the Commission's policy on public meetings to provide the meeting notice and agenda in the background information of the ADAMS package. Other related documents are normally not necessary because the inspection report and transmittal letter typically provide sufficient information. However, if a separate agenda is created, a WordPerfect file should be sent to "OEWEB" for posting on the Enforcement Web site.

4.1.4 Conducting PECs and Regulatory Conferences

PECs and Regulatory Conferences should be conducted according to the following guidelines:

- a. Conferences are normally conducted in the regional offices.
- b. The region should consult with OE prior to scheduling the conference when:
 1. There are special circumstances where the agency determines that it would be beneficial to the enforcement process to conduct the conference at the licensee's facility; or

2. It would be more practical for the agency to conduct the conference by telephone or video.
 3. It is up to the Regional Administrator's discretion to allow a particular conference to be conducted by telephone or video conference.
- c. Members of the public will be allowed access to the NRC regional offices to attend open conferences in accordance with the "Standard Operating Procedures For Providing Security Support For NRC Hearings And Meetings" published November 1, 1991 (56 FR 56251) which provides that visitors may be subject to personnel screening, that signs, banners, posters, etc., not larger than 18" will be permitted, and that disruptive persons may be removed.
- d. The Regional Administrator should determine the appropriate member of regional management to serve as the presiding official at the conference.
1. The presiding official should not normally be below a Deputy Division Director; however,
 2. It may be appropriate for a Branch Chief to serve as the presiding official for certain conferences involving materials licensees.
- e. For those conferences in which safeguards information is to be discussed at the conference, NRC staff should not participate by telephone, for security reasons.
1. If such participation is necessary, it should be done in accordance with [Management Directive 12.4, "NRC Telecommunications System Security Program,"](#) and [12.6, "NRC Sensitive and Unclassified Information Security Program."](#)
 2. If security issues (not directly related to safeguards information) are the subject of the conference, NRC staff should not participate by telephone unless a compelling reason exists and safeguards information will clearly not be discussed.
- f. The presiding NRC official, Enforcement Coordinator, or Enforcement Specialist should:
1. Announce the meeting as an open or closed predecisional enforcement conference;
 2. Discuss the purpose of the conference;
 3. Inform the licensee and public attendees that the decision to hold the conference does not mean that the agency has determined that violations have occurred or that enforcement action will be taken;

☞ Although some conferences may warrant transcription, conferences are not conducted under oath. However, if warranted, the staff should be clear that whether or not a statement is under oath, a false statement on a material matter may be subject to civil and criminal prosecution.

4. Inform the public attendees (for open conferences) that the conference is a meeting between the NRC and the licensee and that the meeting is open for public observation but not participation; and
 5. Briefly explain the enforcement process, focusing on the portions of the Enforcement Policy that are applicable to the issues to be discussed.
 - (a) When NRC staff is participating by video or telephone on a case involving security, the presiding official should also announce that safeguards information should not be discussed during the conference, for security reasons.
 - (b) If the conference is open, the region should ensure that it has copies available of the [Enforcement Policy](#), inspection report, and slides to be discussed.
 - g. The region should briefly discuss the apparent violations and explain the agency's basis for concern.
 1. The level of detail to be discussed is related to the complexity and significance of the issues.
 2. Most of the detailed information will have been included in the inspection report.
 3. The discussion should include the root causes of the apparent violations and the corrective actions planned or taken.
 - (a) Corrective actions considered by the NRC to be inadequate (or only marginally acceptable) should be emphasized.
 - (b) It is helpful to have a slide of the apparent violations, especially in complex cases, to guide the discussion.
 - h. The region should address the apparent safety significance of the issues.
 1. The region should not specifically discuss severity level categorizations, civil penalty amounts, or the nature or content of any orders.
 2. If the region chooses to use slides or handouts for any part of its presentation, they should contain the following note: **"The apparent violations discussed in this predecisional enforcement conference are subject to further review and are subject to change prior to any resulting enforcement action."**
 - i. The licensee should be encouraged to:
 1. Present its understanding of the facts and circumstances surrounding the apparent violations;
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2. Discuss whether it agrees with the NRC's understanding of the facts, the root cause(s), the safety significance, and the immediate and long-term corrective actions taken or planned to be taken; and
3. Present other information relevant to the agency's enforcement decision, e.g.:
 - (a) The licensee's perspective on the severity of the issue;
 - (b) The factors that the NRC considers when it determines the amount of a civil penalty that may be assessed (e.g., missed opportunities to identify the violation sooner); and
 - (c) Any other factors that may warrant enforcement discretion.
- j. The licensee should understand that the conference is a means of providing to the NRC information it believes the agency should consider in determining the appropriate enforcement action.
 1. The conference is not a meeting to negotiate sanctions with the staff, nor should it be used as a forum for protracted debate.

✓ PECs and regulatory conferences should normally not last longer than three hours.)
 2. Once the pertinent facts have been established, the presiding official must recognize differences of opinion and keep the conference productive.
- k. The region should normally take a short break prior to the conclusion of the conference to meet with the staff to ensure that the staff has no outstanding questions.
- l. The region should provide closing remarks. The presiding NRC official, Enforcement Coordinator, or Enforcement Specialist should include in those remarks, a reminder for the licensee and public attendees that:
 1. The apparent violations discussed are subject to further review and are subject to change prior to any resulting enforcement action; and
 2. The statements of views or expressions of opinion made by NRC employees at the predecisional enforcement conference, or the lack thereof, are not final conclusions.
- m. After the business portion of an open meeting has been concluded, the presiding NRC official, Enforcement Coordinator, or Enforcement Specialist should announce that the staff is available to address comments or questions from the public. Although licensees are not obligated, they may respond to questions if they choose to do so.

4.1.5 Transcribing PECs and Regulatory Conferences

- a. Under certain circumstances, the NRC may choose to transcribe a predecisional enforcement conference.
- b. Absent coordination with OE, conferences should be transcribed for cases involving:
 - A licensed operator
 - A licensee employee who may have committed a willful violation
 - A significant case in which a record is warranted
 - A case involving an OI report, or a case involving discrimination
 - Any other case that the region believes should be transcribed, after consultation with OE
- c. Transcribed conferences should normally be closed meetings between the NRC and the licensee. As such, licensees will not be allowed to transcribe or record a conference.
- d. Transcripts should not be released without the approval of the Director, OE, and only after any associated enforcement action has been issued.
 1. If the licensee or any individual at the conference is subsequently provided a copy of the transcript, whether by the staff's offer or the individual's request, the individual should be informed that a copy will also be made available to the Public (subject to removal of privacy information, proprietary information, etc.).
 2. Transcripts for open conferences may be made available to the Public as soon as they are available from the court reporter.

4.1.6 PEC and Regulatory Conference Summaries

- a. After the PEC or Regulatory Conference has been held, the region should prepare a conference summary (see forms in Appendix D).
- b. The conference summary documents the proceedings and serves as a vehicle for making the licensee's handouts and the NRC's outline or agenda available to the Public.
- c. In most cases, the licensee's presentation handouts (and the NRC's handouts, if used) will provide sufficient information to summarize the conference proceedings.
- d. The summary should include a brief description of the following information (if not already addressed in the licensee's handouts), including:
 6. The licensee's position (i.e., if the licensee agrees with the findings in the inspection report, or if the licensee takes issue with the apparent violation(s)).
 7. Any significant additions or corrections to the factual information in the inspection report.
 3. Any significant additional information that affects the significance of each violation.

4. The short-term and long-term corrective actions the licensee has implemented or has committed to implement. (This description should be sufficient for the staff to judge the corrective action as part of the civil penalty assessment process.)
- e. The conference summary should be as brief as possible.
- f. The region should include the conference summary as part of the background material submitted with proposed escalated enforcement actions. The summary should be sent to the licensee either before or when the enforcement action is issued.

☞ The Conference Summary should not include predecisional, safeguards, safeguards information - modified handling (SGI-M), Privacy Act information, or information which could be considered sensitive or proprietary.

4.2 Enforcement and SDP Caucuses

- a. **Enforcement caucuses** are meetings that are held subsequent to a predecisional enforcement conference or following receipt of a licensee's response to a choice letter, to discuss whether new information or perspectives were obtained warranting reconsideration of the enforcement approach for the case and whether, for choice letter responses, a conference should be conducted.
- b. **SDP/enforcement caucuses** are meetings that are held subsequent to a regulatory conference or following receipt of a licensee's response to a choice letter, to discuss whether new information or perspectives were obtained warranting reconsideration of the significance determination for the case and whether, for choice letter responses, a conference should be conducted.
1. Because the outcome of the SDP informs the enforcement process, a secondary purpose for such meetings is to discuss and reach agreement on an enforcement approach for any violations that might be associated with the inspection findings.
 2. Although these caucuses are similar to enforcement caucuses in many respects, specific guidance for SDP caucuses is included in [MC 0609, Attachment 0609.01](#), dated 06/20/03.

4.2.1 Participating in Enforcement and SDP Caucuses

- a. Participation in enforcement and SDP caucuses should be in accordance with the following guidelines:
1. **Region:** The region should schedule a caucus as soon after a conference or receipt of a licensee's response to a choice letter as possible. When possible, the caucus should occur immediately following the conference.

- (a) The region should notify OE, and the applicable program office Enforcement Coordinator(s).
 - (b) The region should invite the Assistant General Counsel for Materials Litigation and Enforcement and the applicable OI investigator and Regional Field Office Director for caucuses involving willfulness.
 - (c) It is expected that the region will be represented by a person at the Division Director level or higher.
 - (d) It is important to recognize that the regional caucus participants provide a recommendation to the Regional Administrator, i.e., their position does not represent the final region position.
2. **OE:** Enforcement Specialists should attend all caucuses.
 - (a) If OE management did not participate in the caucus, it will provide its position to the region within one day of the meeting.
 - (b) The decision will be documented on a Strategy Form.
 - (c) A final decision on the enforcement action is not to be made until OE approves the enforcement strategy as documented on the Strategy Form.
 3. **Program Office:** The program office should be invited to participate in caucuses; however, attendance is not mandatory except when the program office is responsible for the allegation or inspection activity (in which case the program office assumes the role of the regional office).
 - (a) The NRR, NMSS, and NSIR Enforcement Coordinators are responsible for arranging for participation by the appropriate and necessary program office staff; and
 - (b) For ensuring that the staff has necessary materials in advance of the meeting (e.g., conference handouts).
 4. **OGC:** OGC (Assistant General Counsel for Materials Litigation and Enforcement) should participate in caucuses involving willfulness and other cases with potential issues of legal significance.
 5. **OI:** OI (applicable investigator and Field Office Director) should be invited if there are questions as to OI findings.
- b. In evaluating the appropriateness of the proposed enforcement strategy, program office participants should focus on whether:
 1. The violations are technically accurate and factual; and
-

2. The enforcement strategy is consistent with the program office's policy, guidance, position, and past practice.
- c. If program office participants disagree with the enforcement strategy discussed during the caucus, they are responsible for elevating their concerns to program office management (i.e., the Associate Director for Operating Reactor Oversight and Licensing for NRR cases; the applicable Division Director for NMSS cases; or the Director, Division of Security Operations, NSIR).

4.2.2 Enforcement and SDP Caucus Outcome

- a. Subsequent to an enforcement or SDP caucus involving OE participation, OE will amend (as warranted) its understanding of the enforcement strategy that was agreed upon during the enforcement caucus by completing the lower portion of the Strategy Form.
 1. OE will send the form to the region and provide it to the program office (through its Enforcement Coordinator).
 2. The form is used to:
 - (a) Brief the Regional Administrator, the Director, OE (if he or she did not participate in the caucus), the Associate Director for Operating Reactor Oversight and Licensing, NRR, the applicable Division Director in NMSS, and the Director, Division of Nuclear Security, NSIR, if warranted; and
 - (b) Subsequently develop the enforcement action and the enforcement action transmittal letter.
- b. Depending on the information gathered during the conference or provided in the licensee's response to the choice letter, and the discussions in the caucus, the staff will determine:
 1. The level of headquarters' review that is necessary for the case; and
 2. One of several outcomes:
 - (a) **The staff concludes that no violation occurred.**
 - (1) OE will document the conclusion of the enforcement caucus regarding the disposition of the issue by completing the Strategy Form.
 - (2) OE will send the form to the region and make it available to the program office and OGC.
 - (3) The region should inform the licensee in writing that the NRC does not intend to issue enforcement action.

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- (4) The region may use the information in the Predecisional Enforcement Conference Summary to clarify why a citation was not issued.
- (b) **The staff concludes that non-escalated enforcement action should be proposed.**
- (1) OE will document the conclusion of the enforcement caucus regarding the disposition of the issue by completing the Strategy Form.
- (2) OE will send the Strategy Form to the region, the program offices, and OGC.
- (3) The regions may generally issue the non-escalated enforcement action based on region/OE/program office agreement on the Strategy Form.
- ☞ In special cases, OE may request that the actual enforcement action be submitted for review and approval prior to issuing a non-escalated NOV that was the subject of a predecisional enforcement conference.
- (4) The region should include an explanation in the cover letter to the licensee of why non-escalated action was appropriate in the particular case.
- (5) The final action should be signed by someone at least at the level of the presiding official at the predecisional enforcement conference and should be sent to OE to close out the EA number.
- (c) **The staff concludes that escalated enforcement action should be proposed.**
- (1) OE will document the conclusion of the enforcement caucus regarding the disposition of the issue by completing the Strategy Form.
- (2) OE will send the form to the region and make it available to the program office and OGC.
- (3) The region should prepare the appropriate escalated enforcement action.
- (d) **Additional facts are disclosed or developed (at or after the conference) that could lead to additional violations.**
- (1) Special efforts should be taken to substantiate these violations before they are included in the proposed enforcement action.
- (2) It may be appropriate to contact the cognizant licensee official, by at least a telephone conference call, to:
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- (a) Discuss the apparent violation before it is formalized; and
 - (b) Provide any additional information that may be relevant.
 - (3) New EA numbers should be assigned to any additional Severity Level I, II, III violations or problems that are proposed with the action.
 - (4) Strategy Forms should be prepared and updated, as appropriate.
 - (e) **The staff concludes that a conference should be conducted, or if the licensee requests a conference.**
 - (1) The region should arrange for a conference with the licensee as soon as possible.
 - (2) A conference may be necessary if the staff concludes that the documented corrective action is not sufficiently prompt and comprehensive such that a civil penalty may be warranted.
 - (3) The Strategy Form should be updated to reflect the information.
 - (f) **The staff concludes that an additional caucus or discussion is necessary.**
 - (1) The same principal caucus participants should attend if practicable.
 - (2) Other participants, to the extent that they might have information relevant to the issues to be discussed, should attend if practicable.
 - (3) All of the original participants need not be present to conduct a subsequent caucus or discussion.
 - (4) The Enforcement Specialist should make available any previous Strategy Form(s) to support discussions regarding the case.
 - c. It is not always necessary to hold a new caucus to change a past agreement recorded on a Strategy Form.
 - 1. OE management can agree to change an agreement as a result of telephone calls or meetings outside the caucus process.
 - 2. After a subsequent caucus or substantive discussion, the Strategy Form will be:
 - (a) Updated noting the outcome of the meeting, including a brief explanation of the reason for any change in enforcement strategy; and
 - (b) Distributed so that the region, program office, and OGC are aware of the change and can comment, if desired.
-

3. Following receipt of the revised Strategy Form, it is the responsibility of the principal participants to verify that the revised strategy is acceptable to the office or region.
 - (a) The principal participants are responsible for discussing, as warranted, changes to previously agreed upon strategy with the prior caucus participants from their office or region who may not have been involved in the subsequent caucus or discussion.
 - (b) The regional principal participants should discuss, as warranted, the issues with OI.
 - d. Disagreements with the revised strategy should be handled as discussed below:
 1. If the Regional Administrator, the Associate Director for Operating Reactor Oversight and Licensing for NRR cases, the applicable Division Director for NMSS cases, or the Director of the Division of Security Operations for NSIR cases disagree on enforcement strategy issues such as significance, SDP characterization, severity level, civil penalty assessment, or enforcement discretion:
 - (a) The Director, OE, must be informed as soon as possible, and normally no later than 24 hours, after receiving OE's summary of the enforcement strategy documented on the Strategy Form.
 - (b) In the case of a regional disagreement, the Regional Administrator and Director, OE, should confer and either resolve their differences or promptly escalate the matter to the DEDO. (Depending on the nature of the regional disagreement, OE may arrange for program office participation.)
 - (c) In the case of a program office disagreement, the Associate Director for Operating Reactor Oversight and Licensing for NRR cases, the applicable Division Director for NMSS cases, or the Director of the Division of Security Operations for NSIR cases, should:
 - (1) Confer with the Director, OE, and the Regional Administrator to resolve their differences; or
 - (2) The Director, OE, will promptly escalate the matter to the DEDO.
 - e. Based on the outcome of these discussions, if warranted, OE will:
 1. Revise the summary of the agreed upon enforcement strategy on the Strategy Form;
 2. Send it to the region; and
 3. Make the revised Strategy Form available to the program office and OGC.
- ☞ If, as discussed in this section, the Director, OE, cannot resolve an enforcement strategy issue with the Regional Administrator, the Director, OE, may request that the complete case (including the transmittal letter to the licensee) be submitted to headquarters for review and approval prior to issuance.

- f. Depending on the circumstances of the case, OE will decide whether:
 - 1. Agreement on the Strategy Form is sufficient; or
 - 2. The actual enforcement action package needs to be submitted to headquarters for review and approval prior to issuance.

4.3 Determining Whether a Civil Penalty Should Be Proposed

- a. Civil penalties are normally assessed for:
 - 1. Severity Level I and II violations;
 - 2. Knowing and conscious violations of the reporting requirements of section 206 of the Energy Reorganization Act; and
 - 3. Failure to make the required notifications that impact the ability of Federal, State and local agencies to respond to an actual emergency preparedness event (site area or general emergency).
- b. Civil penalties are considered for Severity Level III violations.
- c. Civil penalties are considered for violations associated with red, yellow, or white SDP inspection findings evaluated through the ROP's SDP that involve actual consequences, such as an overexposure to the public or plant personnel above regulatory limits, or releases in excess of regulatory limits.
- d. For violations that impact the regulatory process or that are willful and therefore assessed under "traditional enforcement," the SDP should be used to risk inform the significance of the underlying violation or issue to the extent possible.
- e. The staff should consider the SDP output in conjunction with the guiding principles for assessing significance and the guidance included in the Supplements of the Enforcement Policy to determine the appropriate severity level.
- f. The following steps should be taken to determine whether a civil penalty should be proposed for the violation.
 - Step 1: Determine the base civil penalty appropriate for the significance of the violation and the class of licensee.
 - Step 2: Complete the civil penalty assessment process, which considers:

☞ Civil penalties **are not** normally proposed for violations associated with low to moderate, or greater safety significant SDP findings absent actual consequences.

- Whether (for a non-willful Severity Level III issue) the licensee has had any previous escalated enforcement action (regardless of the activity area) during the past two years or past two inspections, whichever is longer;
 - Whether the licensee should be given credit for actions related to identification;
 - Whether the licensee's corrective actions are prompt and comprehensive; and
 - Whether, in view of all the circumstances, the matter in question requires the exercise of discretion.
- Step 3: Compare the amount of the civil penalty resulting from the civil penalty process described above with the amount allowed by statute, to ensure that the civil penalty amount actually issued is within the statutory maximum.
- Step 4: Determine whether an escalated NOV should be issued with or without a civil penalty based on the outcome of the civil penalty process.

4.3.1 Base Civil Penalty

- a. The NRC imposes different levels of penalties for different severity level violations and different classes of licensees, vendors, and other persons.
- b. Violations that involve loss, abandonment, or improper transfer or disposal of a sealed source or device are treated separately, regardless of the use or the type of licensee.
- c. After determining that a civil penalty should be proposed with an NOV, the next step in the civil penalty process is to determine the base civil penalty for the violation.
 1. Tables 1A and 1B in the Enforcement Policy provide the base civil penalties for various reactor, fuel cycle, and materials programs, and for the loss, abandonment or improper transfer or disposal of a sealed source or device.
 2. The structure of these tables takes into account both the gravity of the violation and the licensee's ability to pay, i.e., operations involving greater nuclear material inventories and greater potential consequences to the public and licensee employees receive higher civil penalties.
 3. Civil penalties issued to individuals are rare and are determined on a case-by-case basis.

4.3.1.1 Ability to Pay and Size of Operation

- a. Although Tables 1A and 1B in the Enforcement Policy are structured to take into account as a primary consideration, the gravity of a violation, and as a secondary matter, the licensee's ability to pay, there may be circumstances that warrant an adjustment to the base civil penalty or consideration of payment of a civil penalty over time.

1. It may be appropriate to increase the size of the base penalty on the basis of the amount of nuclear materials inventoried, the potential hazards associated with them, and the size and nature of the licensee operation and program.
 - (a) Increasing the penalty requires OE approval and may require Commission consultation.
 - (b) Orders, rather than civil penalties, should be used when the intent is to suspend or terminate licensed activities.
 - (c) The deterrent effect of civil penalties is best served when the amounts take into account the licensee's ability to pay.
- b. If a licensee can demonstrate financial hardship, the NRC will normally consider payments over time which includes interest and administrative charges, rather than reducing the amount of the civil penalty.
 1. If, after consultation with OE, payments over time or reduction of the penalty appears appropriate, the licensee will normally be required to address why it has sufficient resources to safely conduct licensed activities and pay license and inspection fees, e.g., a DFI can be used to require the licensee to respond to such an inquiry.

☞ If payment of a civil penalty could impair the licensee's ability to safely conduct licensed activity, the staff should consider whether the licensee should be allowed to maintain its license, given its questionable financial stability.
 2. The licensee should be requested to provide the NRC with written evidence to demonstrate that payment of the civil penalty would substantially affect its ability to remain in business or would substantially affect its ability to safely conduct licensed activities.
 - (a) The licensee must support its position with documentation for the past three years (such as profit and loss statements showing income and expenses including such items as gross sales and salaries, balance statements showing assets and liabilities, auditor's reports, and tax returns or other evidence) and must also provide a statement from at least one financial institution that it could not obtain a loan.
 - (b) If the licensee's submittal does not support its claim, the responsible office should impose the civil penalty and inform the licensee that NRC evaluation of the submitted evidence does not support the licensee's claim.
 - (c) If the licensee's submittal supports its claim, the civil penalty should be imposed over a time-frame that is consistent with NRC's evaluation of the licensee's evidence and should provide the licensee with the basis for the NRC's conclusion.

- (1) The regional office should prepare the terms to be included in a Promissory Note in Payment of the Civil Penalty (see the forms in Appendix B).
- (2) The Accounts Receivable Team, Division of Financial Management in the Office of the Chief Financial Officer (CFO/DFM/ART) will prepare all promissory notes using the terms that the regional office provides, i.e., the length of time, the minimum monthly payment, the payment schedule, etc.
- (3) OE will issue the note to the licensee.
- (4) After the licensee signs and returns the note to the NRC, the Director, OE, counter-signs the note and OE forwards a copy to the licensee.

4.3.1.2 Small Business Regulatory Enforcement Fairness Act (SBREFA)

- a. The NRC is subject to the Small Business Regulatory Enforcement Fairness Act (SBREFA).
- b. Among the requirements of the SBREFA, the NRC must consider the SBREFA in taking civil penalty actions against small entities.

✓ If a small entity claims hardship:

- The Region may propose up to a 50% reduction to the civil penalty
- For proposed reductions of more than 50% and up to waiving the fine, the licensee must also demonstrate that a hardship exists by meeting the criteria for financial hardship
- The staff should note that payment-over-time is an option specifically tailored for small businesses.

1. The NRC's Enforcement Policy civil penalty structure takes into account the size of the licensee by virtue of the nature of the operation, the significance of the violations, and consideration of factors such as identification, corrective action, licensee history, and willfulness or other particularly poor performance.

2. SBREFA also addresses financial hardship.

- (a) In reaching decisions concerning enforcement actions, the staff should keep the intent of SBREFA in mind.

☞ Not all small entities are "equal." For the purpose of reducing licensing fees, small entities can include fairly large companies, corporations, etc.; however, when considering whether to reduce the amount of a material user's civil penalty, the licensee must be, in fact, a small entity.

- (b) There may be cases where, after considering the normal adjustment factors and the size of a qualified small entity to whom a civil penalty may be issued, the staff believes that the penalty should be reduced or eliminated. In those cases, it is appropriate to propose such a modification based on the intent of SBREFA.

- c. Any adjustments to the proposed civil penalty under SBREFA would be applied as an exercise of discretion and the appropriate Enforcement Action Tracking System (EATS) keyword should be entered.

4.3.2 Civil Penalty Assessment Process

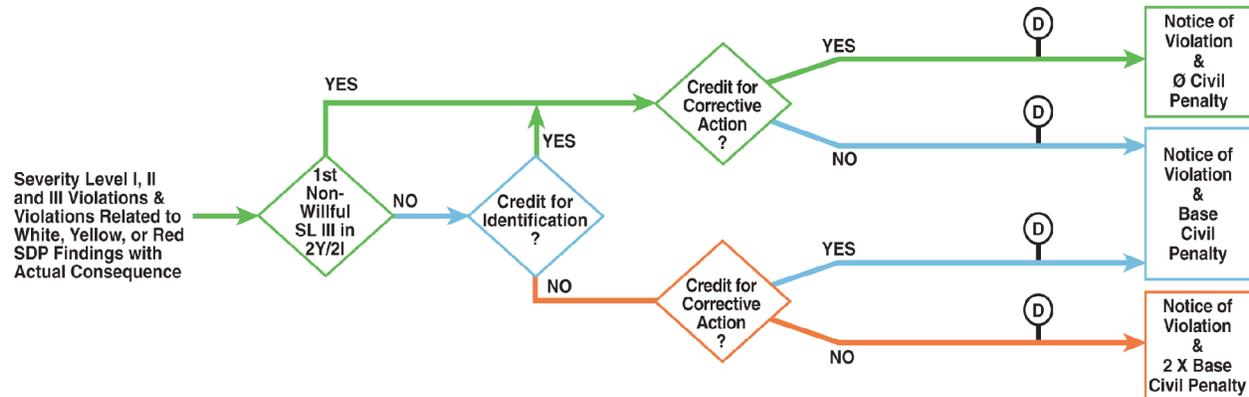


Figure 4-1: This flow chart is a graphic representation of the civil penalty assessment process.

- a. The civil penalty assessment process is addressed in the Enforcement Policy.
- b. In an effort to emphasize the importance of adherence to requirements and reinforce prompt self-identification of problems and root causes and prompt and comprehensive correction of violations, the NRC reviews each proposed civil penalty on its own merits.
- c. The civil penalty assessment process considers these decisional points:
1. Is this the first non-willful Severity Level III enforcement action (regardless of the activity area) that the licensee has had during the past two years or past two inspections the "Standard Operating Procedures For Providing Security Support For NRC Hearings And Meetings" (whichever is longer)?
 2. Should the licensee be given credit for actions related to identification? (Only consider if the answer to the previous question is no.)
 3. Are the licensee's corrective actions prompt and comprehensive?
 4. In view of all the circumstances, does the matter in question require the exercise of discretion, e.g., Severity Level I and II violations should normally result in a civil penalty?

- d. Although each of these decisional points may have several associated considerations for any given case, the outcome of the assessment process for each violation or problem, absent the exercise of discretion, is limited to one of the following three results:
- No civil penalty
 - A base civil penalty
 - Twice the base civil penalty.

4.3.2.1 Initial Escalated Action

- a. The NRC will consider whether the licensee's corrective action for the present violation or problem is reasonably prompt and comprehensive when:
1. The NRC determines that a non-willful Severity Level III violation or problem has occurred; and
 2. The licensee has not had any previous Severity Level I, II, or III escalated actions (regardless of the activity area) for this site during the past two years or two inspections, whichever is longer.
 - (a) This includes new licensees who have not been in existence during the past two years or for two inspections (provided that they have not had previous escalated actions).

✓ Civil penalties are not normally assessed for SDP cases.
 - (b) Because a new licensee is involved, the staff should consider whether the apparent significance of the violation requires the staff to:
 - (1) Exercise discretion to impose a civil penalty; or
 - (2) Take even more stringent action to address the apparent poor performance by a new licensee.
 - (c) This criterion should also be considered for license transfers and when a licensee moves, including situations where the license is terminated and a new license is obtained.
 - (1) This is appropriate if the facility personnel, procedures, and equipment stay the same after a license transfer or move, thereby making past enforcement history a valid issue.
 - (2) If significant changes have been made in the above areas, consideration of enforcement history may be inappropriate.
- b. This criterion considers past NRC escalated actions with severity levels, i.e., traditional enforcement.

1. It does not include previous escalated enforcement actions issued under the SDP (i.e., NOVs associated with red, yellow, or white SDP findings.)
2. It does not include previous escalated enforcement actions in an Agreement State.
 - (a) Considering previous escalated actions in an Agreement State is not appropriate because of variations in enforcement programs in the different Agreement States.
 - (b) If an Agreement State licensee violates a requirement while working in NRC jurisdiction under reciprocity and the staff is aware of previous escalated action in an Agreement State and the violation is directly repetitive or the enforcement history is particularly poor, the staff *may* consider an adjustment to the civil penalty assessment process by exercising enforcement discretion under the NRC Enforcement Policy.
- c. Using two years as the basis for assessment is expected to cover most situations.
 1. Considering a slightly longer or shorter period might be warranted based on the circumstances of a particular case.
 2. The starting point of this period is when the licensee was put on notice of the need to take corrective action.
 - (a) For a licensee-identified violation or an event, this would be when the licensee is aware that a problem or violation exists requiring corrective action.
 - (b) For an NRC-identified violation, the starting point would be when the NRC puts the licensee on notice, which is typically at the inspection exit meeting, or as part of post-inspection communication.
- d. If the corrective action is judged to be prompt and comprehensive, an NOV normally should be issued with no associated civil penalty. If the corrective action is judged to be less than prompt and comprehensive, the NOV normally should be issued with a base civil penalty.

4.3.2.2 Credit for Actions Related to Identification

- a. **Identification** presumes that the identifier recognizes the existence of a problem, and understands that corrective action is needed.
- b. The civil penalty assessment should normally consider the factor of identification in addition to corrective action when:
 1. A Severity Level I or II violation or a willful Severity Level III violation has occurred;
 2. During the past two years or two inspections, whichever is longer, the licensee has been issued at least one other escalated action; or

3. A licensee has not been in existence during the past two years or for two inspections.
- c. The NRC should consider whether the licensee should be given credit for actions related to identification of the problem requiring corrective action, e.g., if a licensee discovers an issue but fails to recognize that corrective actions are needed, then the licensee may not be deserving of identification credit.
1. Identification and corrective action are separate decisions.
 2. The decision on identification requires considering all the circumstances of identification including:
 - (a) Whether the problem requiring corrective action was:
 - NRC-identified
 - Licensee-identified
 - Revealed through an event
 - (b) Whether prior opportunities existed to identify the problem requiring corrective action, and if so, the age and number of those opportunities;
 - (c) Whether the problem was revealed as the result of a licensee self-monitoring effort, such as conducting an audit, a test, a surveillance, a design review, or troubleshooting;
 - (d) For NRC-identified issues, whether the licensee would likely have identified the issue in the same time-period if the NRC had not been involved;
 - (e) For cases in which the NRC identifies the issue or identifies the overall problem (i.e., a programmatic issue requiring corrective action, consider:
 - (1) Whether the licensee should have identified the issue (and taken action) earlier; and
 - (2) The degree of licensee initiative or lack of initiative in identifying the problem or problems requiring corrective action.

☛ An **event**, as used in this section, means (1) a situation characterized by an active adverse impact on equipment or personnel, readily obvious by human observation or instrumentation, or (2) a radiological impact on personnel or the environment in excess of regulatory limits, such as an overexposure, a release of radioactive material above NRC limits, or a loss of radioactive material, e.g., an equipment failure discovered through a spill of liquid, a loud noise, the failure to have a system respond properly, or an annunciator alarm would be considered an event. Similarly, if a licensee discovered, through quarterly dosimetry readings, that employees had been inadequately monitored for radiation, the issue would normally be considered licensee-identified; however, if the same dosimetry readings disclosed an overexposure, the issue would be considered an event.

- (f) For a problem revealed through an event, the ease of discovery, and the degree of licensee initiative in identifying the root cause of the problem and any associated violations;

☞ In cases where the licensee identifies a noncompliance that has existed for an extended length of time, the ease of identification of the noncompliance should be taken into consideration.

- d. Although some cases may consider all of the above factors, the importance of each factor will vary based on the type of case as discussed in the following general guidance:
1. **Licensee-Identified:** When a problem requiring corrective action is licensee-identified (i.e., identified before the problem has resulted in an event), the NRC should normally give the licensee credit for actions related to identification, regardless of whether prior opportunities existed to identify the problem.
 2. **Identified Through an Event:** When a problem requiring corrective action is identified through an event, the decision on whether to give the licensee credit for actions related to identification normally should consider:
 - (a) The ease of discovery;
 - (b) Whether the event occurred as the result of a licensee self-monitoring effort (i.e., whether the licensee was "looking for the problem");
 - (c) The degree of licensee initiative in identifying the problem or problems requiring corrective action; and
 - (d) Whether prior opportunities existed to identify the problem.
 - (1) Any of these considerations may be overriding if particularly noteworthy or particularly egregious, e.g., if the event occurred as the result of conducting a surveillance or similar self-monitoring effort (i.e., the licensee was looking for the problem), the licensee should normally be given credit for identification.
 - (2) As a second instance, even if the problem was easily discovered (e.g., revealed by a large spill of liquid), the NRC may choose to give credit because noteworthy licensee effort was exerted in ferreting out the root cause and associated violations, or simply because no prior opportunities (e.g., procedural cautions, post-maintenance testing, quality control failures, readily observable parameter trends, or repeated or locked-in annunciator warnings) existed to identify the problem.
 3. **NRC-Identified:** When a problem requiring corrective action is NRC-identified, the decision on whether to give the licensee credit for actions related to identification should

normally be based on an additional question, i.e., should the licensee have reasonably identified the problem (and taken action) earlier?

- (a) In most cases, this reasoning may be based simply on the ease of the NRC inspector's discovery (e.g., conducting a walkdown, observing in the control room, performing a confirmatory NRC radiation survey, hearing a cavitating pump, or finding a valve obviously out of position). In some cases, the licensee's missed opportunities to identify the problem might include a similar previous violation, NRC or industry notices, internal audits, or readily observable trends.
 - (b) If the NRC identifies the violation but concludes that, under the circumstances, the licensee's actions prior to identification were reasonable and may have, in fact, led to the identification, the matter can be treated as licensee-identified for purposes of assessing the civil penalty. In such cases, the question of identification credit shifts to whether the licensee should be penalized for NRC's identification of the problem.
4. **Mixed Identification:** For "mixed" identification situations (i.e., where multiple violations exist, some NRC-identified, some licensee-identified, or where the NRC prompted the licensee to take action that resulted in the identification of the violation), the NRC's evaluation should normally determine whether the licensee could reasonably have been expected to identify the violation in the NRC's absence.
- (a) This determination should consider, among other things:
 - (1) The timing of the NRC's discovery;
 - (2) The information available to the licensee that caused the NRC concern;
 - (3) The specificity of the NRC's concern;
 - (4) The scope of the licensee's efforts;
 - (5) The level of licensee resources given to the investigation; and
 - (6) Whether the NRC's path of analysis had been dismissed or was being pursued in parallel by the licensee.
 - (b) In some cases, the licensee may have addressed the isolated symptoms of each violation (and may have identified the violations), but failed to recognize the common root cause and taken the necessary comprehensive action. Where this is true, the decision on whether to give licensee credit for actions related to identification should focus on identification of the problem requiring corrective action (e.g., the programmatic breakdown).
 - (c) Depending on the chronology of the various violations, the earliest of the individual violations might be considered missed opportunities for the licensee to have identified the larger problem.
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5. Missed Opportunities to Identify:

- (a) Missed opportunities include prior notifications or missed opportunities to identify or prevent violations through, e.g.:
 - (1) Normal surveillances, audits, or quality assurance (QA) activities;
 - (2) Prior notice i.e., specific NRC or industry notification; or
 - (3) Other reasonable indications of a potential problem or violation, such as observations of employees and contractors, and failure to take effective corrective steps.
 - (b) In assessing this factor, consideration will be given to, among other things:
 - (1) The opportunities available to discover the violation;
 - (2) The ease of discovery;
 - (3) The similarity between the violation and the notification;
 - (4) The period of time between when the violation occurred and when the notification was issued;
 - (5) The action taken (or planned) by the licensee in response to the notification;
 - (6) The level of management review that the notification received (or should have received).
 - (c) Missed opportunities may include findings of the NRC, the licensee, or industry made at other facilities operated by the licensee where it is reasonable to expect the licensee to take action to identify or prevent similar problems at the facility subject to the enforcement action at issue.
 - (d) The evaluation of missed opportunities should normally depend on whether the information available to the licensee should reasonably have caused action that would have prevented the violation.
 - (e) Missed opportunities is normally not applied where the licensee appropriately reviewed the opportunity for application to its activities and reasonable action was either taken or planned to be taken within a reasonable time.
 - (f) In some situations the missed opportunity is a violation in itself. In these cases, unless the missed opportunity is a Severity Level III violation in itself, the missed opportunity violation may be grouped with the other violations into a single "problem."
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- (g) If the missed opportunity is the *only* violation, then it should not normally be counted twice (i.e., both as the violation and as a missed opportunity--"double counting") unless the number of opportunities missed was particularly significant.
 - (h) The length of time during which the licensee failed to discover the violation should also be considered. A two-year period should generally be used for consistency in implementation.
- e. When the NRC determines that the licensee should receive credit for actions related to identification and the corrective action is determined to be reasonably prompt and comprehensive, the civil penalty assessment should normally result in either no civil penalty or a base civil penalty.
 - f. When the licensee is not given credit for actions related to identification, the civil penalty assessment should normally result in an NOV with either a base civil penalty or a base civil penalty escalated by 100%, depending on the quality of corrective action, because the licensee's performance is clearly not acceptable.

4.3.2.3 Examples Where Identification Is Considered

- a. Generally, if the licensee identifies a problem before an event occurs or before the NRC identifies it, the licensee should get credit for the identification (even if missed opportunities existed, including the failure of past corrective action for similar violations).
 - 1. If the violation is identified as the result of an event associated with normal operations, in contrast to an event associated with an assessment activity such as a surveillance test, missed opportunities should be considered.
 - 2. If the NRC identifies the violation, it is appropriate to consider whether the licensee should have identified the violation.
 - (a) The actual application of this factor will be a function of the circumstances of the case, the issues associated with identification, and the regulatory message warranted by the facts of the case.
 - (b) Identification presumes recognition that corrective action is required.
- b. Recognizing that application of the identification factor will require applying judgment to the particular set of facts and circumstances in each case, the following guidance should not be viewed as controlling or exhaustive:

IS Identification presumes that the identifier recognizes the existence of a problem, and understands that corrective action is needed.

1. Situations In Which the Licensee Should Be Given Credit:

- (a) Violations identified as a result of surveillances or tests, when a parameter check is required by the procedure and limits or ranges do not meet regulatory requirements.
- (b) Discovery of inoperable equipment during surveillance testing performed to determine the operability of that equipment. If as a result of the surveillance testing, an event occurs because of other equipment (i.e., equipment not being tested) failing, missed opportunities should be considered when evaluating identification for the failure of the "other" equipment.
- (c) Violations identified during a surveillance test where an evolution or process that is being tested does not proceed as expected, e.g., a liquid spill due to a mispositioned valve.
- (d) Disclosure of a fitness-for-duty violation during routine testing.
- (e) Identification of a violation as a result of the licensee followup of safety concerns raised by an employee of the licensee.
- (f) Violations identified in audit findings, deficiency reports, or contractor reviews, in which the condition adverse to quality was not corrected in a timely manner, but was later disclosed by a licensee review before an event occurred.
- (g) Violations identified as the result of procedurally required checks of a medical treatment plan before treatment occurs, or as the result of daily checks of radiography equipment before the equipment is used.
- (h) Cases in which, in response to an event, a licensee investigation identifies violations that were not involved in or did not contribute to the event.
- (i) Violations identified as the result of a licensee's review of, e.g., generic communications, NRC Information Notices, reports generated by outside or industry groups, etc.
- (j) If the NRC finds a violation prior to the licensee's identification of it, but the licensee was aggressively pursuing the same issue as the result of an NRC Information Notice and likely would have found it within a reasonable time, the licensee should get credit for its identification activities.

2. Situations In Which Missed Opportunities Should Be Considered Before Giving the Licensee Credit for Identification:

- (a) Violations identified as the result of an event that was readily obvious by human observation or mechanical instrumentation such as a reactor trip, or leak, spills, or annunciator alarms.

- (b) As the result of a lost or damaged gauge, the licensee identifies a failure to maintain constant control over a gauge containing byproduct material.
- (c) Discovery of an overexposure documented in a dosimetry report.
- (d) Licensee identifying the loss of control of material after being informed by a member of the public that material has been found in the environment.
- (e) Receipt of records from the Federal Bureau of Investigations indicating that a person who has been granted unescorted access had a criminal history of which the licensee was not aware, although the information was available in the licensee's records.
- (f) As a result of an event or NRC questions, the licensee identifies violations that it should have found earlier if it had been responsive to previous audits findings, deficiency reports or contractor reviews, where conditions adverse to quality were not corrected in a timely manner.
- (g) Violations that caused or contributed to an event, identified as part of a follow-up to the event.
- (h) Violations identified as part of determining the root causes for a radiation injury to a patient.
- (i) Cases in which the inappropriate location of sources results in a misadministration being disclosed when the source is removed.
- (j) Cases in which an overexposure is identified after reading personal dosimetry or data documented in dosimetry reports following an event where, due to the event, the potential for an overexposure exists.

3. NRC-Identified Situations:

- (a) Cases in which a licensee does not appear to have been pursuing a matter on its own but, due to concerns raised by the NRC, identifies:
 - (1) Violations related to equipment failures when the NRC has questioned operability of the equipment; or
 - (2) Violations of reporting requirements found when the NRC requested information on the event.
- (b) Violations related to an event would be considered NRC-identified if:

- (1) The violation is subsequently discovered by the NRC during event follow-up where the licensee failed to initiate reviews or investigations that would have reasonably identified the violation, e.g., a misadministration may have occurred that the licensee attributes to a failure to follow procedure, and does not pursue the matter further.
- (2) The NRC finds that an underlying root cause violation exists (e.g., a training violation), but the licensee has not pursued it.

4.3.2.4 Credit for Prompt and Comprehensive Corrective Action

- a. The purpose of corrective action is to encourage licensees to:
 1. Take the actions necessary immediately upon discovery of a violation that will restore safety and compliance with the license, regulation(s), or other requirement(s); and
 2. Develop and implement (in a timely manner) the corrective actions that will not only prevent recurrence of the violation at issue, but will be appropriately comprehensive, given the significance and complexity of the violation, to prevent occurrence of violations with similar root causes.
- b. Regardless of other circumstances (e.g., past enforcement history, identification, etc.), the licensee's corrective actions should always be evaluated as part of the civil penalty assessment process.
 1. As a reflection of the importance given to this factor, an NRC judgment that the licensee's corrective action has not been prompt and comprehensive will always result in issuing at least a base civil penalty.
 2. In assessing this factor, consideration will be given to:
 - (a) The timeliness of the corrective action (including the promptness in developing the schedule for long term corrective action);
 - (b) The adequacy of the licensee's root cause analysis for the violation, and,
 - (c) The comprehensiveness of the corrective action (i.e., whether the action is focused narrowly to the specific violation or broadly to the general area of concern), given the significance and complexity of the issue.

Even in cases when the NRC, at the time of the predecisional enforcement conference, identifies additional peripheral or minor corrective action still to be taken, the licensee may be given credit in this area, as long as the licensee's actions addressed the underlying root cause and are considered sufficient to prevent recurrence of the violation and similar violations.

- c. Normally, the judgment of the adequacy of corrective actions will hinge on whether the NRC had to take action to focus the licensee's evaluative and corrective process in order to obtain comprehensive corrective action.
1. This will normally be judged at the time of the predecisional enforcement conference (e.g., by outlining substantive additional areas where corrective action is needed).
 2. Earlier informal discussions between the licensee and NRC inspectors or management may result in improved corrective action, but should not normally be a basis to deny credit for corrective action.
 3. For cases in which the licensee does not get credit for actions related to identification because the NRC identified the problem, the assessment of the licensee's corrective action should begin from the time when the NRC put the licensee on notice of the problem.
 4. Notwithstanding eventual good comprehensive corrective action, if immediate corrective action was not taken to restore safety and compliance once the violation was identified, corrective action would not be considered prompt and comprehensive.
- d. Corrective action for violations involving discrimination should normally only be considered comprehensive if the licensee takes prompt, comprehensive corrective action that:
1. Addresses the broader environment for raising safety concerns in the workplace; and
 2. Provides a personal remedy for the particular discrimination at issue.

✓ In response to violations of 10 CFR 50.59, corrective action should normally be considered prompt and comprehensive only if the licensee makes a prompt decision on operability, and either (1) makes a prompt evaluation under 10 CFR 50.59 if the licensee intends to maintain the facility or procedure in the as found condition; or (2) promptly initiates corrective action consistent with Criterion XVI of 10 CFR 50, Appendix B, if it intends to restore the facility or procedure to the FSAR description.

4.3.3 Assigning Final Civil Penalty Amounts

- a. The statutory maximum civil penalty amount, as established in the 1980 revision to the AEA, is \$100,000 per violation, per day; however, that amount has been periodically adjusted by the Debt Collection Improvement Act of 1996 and is currently \$130,000 per violation, per day.
- b. To calculate the statutory maximum for a given Severity Level I, II, or III problem, each associated violation should be assigned the \$130,000 value, multiplied by the number of days the violation existed, and then added to the civil penalty amounts for the other violations. In other words, the statutory maximum for a given Severity Level I, II, or III

problem is the cumulative result of the number of associated violations and the number of days that each violation existed.

- c. Civil penalties are normally assessed using the process described in the previous section of this manual.
- d. The issuance of civil penalties is intended to be remedial, i.e., to encourage prompt and effective corrective actions and to prevent recurrence.
- e. The NRC reserves the imposition of daily civil penalties up to the statutory maximum for particularly significant violations, e.g., violations with actual consequences to public health and safety or the common defense and security, repetitive significant violations, and willful violations involving senior licensee officials.

☞ The civil penalty assessment process described in this chapter is intended to be a normative standard for most Severity Level III issues. Departures from this process by the exercise of discretion (for either escalation or mitigation of the enforcement action) requires the approval of the Director, OE, and may require approval of the DEDO or EDO and/or notification or consultation with the Commission, as specified in the Enforcement Policy. However, in no instance will a civil penalty for any one violation exceed \$130,000 per day.

4.3.4 Civil Penalty Assessment Process Outcome

Depending on the outcome of the civil penalty assessment process, the staff will conclude that an escalated NOV should be issued without a civil penalty or that an escalated NOV should be issued with a civil penalty.

4.4 Escalated Notices of Violation Without Civil Penalty (NOVs)

- a. Notices of Violation are addressed in the Enforcement Policy.
- b. The procedures for issuing NOVs are set forth in [10 CFR 2.201](#).
- c. An NOV is a formal written citation setting forth one or more violations of a legally binding requirement. An NOV including Severity Level I, II, or III violations is considered escalated enforcement action. An NOV including violations associated with red, yellow, or white SDP findings is also considered an escalated enforcement action.
- d. Escalated NOVs are normally issued subsequent to conferences or after a licensee has had an opportunity to respond to apparent violations in an inspection report. Escalated NOVs are included in the Significant Enforcement Actions collection on the **Enforcement** Web site.

4.4.1 Preparing an Escalated NOV Action

- a. Escalated NOVs without civil penalties should be prepared by using the applicable standard format in Appendix B and the applicable standard citations in Appendix C.
- b. Escalated NOVs should be dated the same date as the cover letter transmitting the enforcement action to the licensee.
- c. The escalated NOV should include the following elements:
 1. A concise, clear statement of the requirement or requirements that were violated, appropriately referenced, paraphrased, or quoted (legal citation for the violation).
 2. A brief statement (usually no more than a few sentences) of the circumstances of the violation, including the date(s) of the violation and the facts necessary and sufficient to demonstrate that the requirement was not met ("contrary to" paragraph).
 - (a) To demonstrate noncompliance, the language of the "contrary to" statement should parallel the applicable language of the requirement.
 - (b) Each violation, including a violation with multiple examples, contains a single "contrary to" statement.
 3. As a general rule, multiple examples of the same violation during the period covered by an inspection should be included in one citation.
 - (a) The "contrary to" paragraph should generally state the violation and then state: "...as evidenced by the following examples:" followed by the examples delineated as 1, 2, 3, etc.
 - (b) When the examples of a particular violation are numerous, sufficient examples should be cited to convey the scope of the violation and to provide a basis for assessing the effectiveness of the licensee's corrective actions. Normally three to five examples should be adequate.
 4. The severity level proposed for the violation or the severity level of the problem when several violations have been grouped.

✓ To avoid the release of predecisional information, the top and bottom of all pages of documents included in escalated enforcement packages should be marked **"Official Use Only - Predecisional Enforcement Information."** In addition, enforcement packages including safeguards information should be clearly marked: "Safeguards Information - Handle in Accordance With 10 CFR 73.21." Internal staff reviews and comments should not be made available to the Public (i.e., should not be publicly available in ADAMS (PARS)).

5. The applicable supplement of the Enforcement Policy under which the violation is categorized or, alternatively, the associated significance of the violation (i.e., red, yellow, or white SDP finding).
 6. A request for the licensee to respond unless the region concludes that a response is not necessary, including:
 - (a) The reason for the violation, or if contested, the basis for disputing the violation;
 - (b) The corrective steps that have been taken and the results achieved;
 - (c) The corrective steps that will be taken to avoid further violations; and
 - (d) The date when full compliance will be achieved.
 7. A waiver, if the region concludes that a response is not necessary based on information regarding the reason for the violation, the corrective actions taken and planned to be taken to correct the violation and prevent recurrence is already addressed on the docket. This alternative requires the licensee to respond if the description does not accurately describe the licensee's corrective action position.
- d. Cover letters that transmit escalated NOV's without civil penalties to licensees should be prepared by the region (see forms in Appendix B).
1. The staff should refer to MC 0612 and MC 0609 for guidance related to the overall structure of the cover letter and content of introductory paragraphs for NOV's associated with SDP findings.
 2. Transmittal letters with and without SDP findings should effectively and succinctly communicate the NRC's perspectives on the violations and the need for corrective action.
 3. In addition to an EA number, cover letters should include a Nuclear Materials Events Database (NMED) number, if applicable.
 4. If possible, the letter should normally be no longer than two pages in length for each violation and should include the following elements:
 - (a) A summary of:
 - (1) The purpose of the inspection;
 - (2) If and how the issue was reported, e.g., 50.72, Licensee Event Report (LER), etc.; and

✓ The EA number should be included for each violation or problem when there is more than one escalated issue in the action.

- (3) When the inspection report(s) related to this action were issued.
 - (b) A discussion of whether a conference was conducted, a choice letter was issued, or a choice call was made, as applicable.
 - (c) A conclusion that a violation(s) occurred and a very brief summary of the event or circumstances that resulted in the violation.
5. For NOV without SDP findings, the discussion should be sufficiently detailed to permit licensee management (and others who may review the action) to understand the safety significance of the violations, including:
- (a) A concise discussion of the safety significance of the violation in terms of whether it is based on the actual safety consequence, potential safety consequence, potential for impacting the NRC's ability to perform its regulatory function, or it was willful and how it relates to severity level categorization;
 - (b) A statement of the base civil penalty amount for the violation or problem and a discussion addressing the applicable routine decisional points in the civil penalty assessment process, i.e.;
 - (1) Whether the licensee has had any escalated actions during the past two years or two inspections (include specific reference to any prior escalated action within two years or two previous inspections);
 - (2) Whether credit was given for identification (address only if the answer to the preceding question is "no;")
 - (3) Whether credit was given for corrective action (include a brief description of corrective actions); and
 - (4) If discretion was exercised, an additional explanation of this decision including a reference to the particular section of the Enforcement Policy discussing the use of discretion;
 - (c) A statement that the NOV is considered escalated action in accordance with the Enforcement Policy because it is associated with a red, yellow, or white SDP finding;
 - (d) A statement associated with not proposing a civil penalty, i.e., to encourage prompt (identification, if applicable) and comprehensive correction of violations, (and to recognize the absence of previous escalated enforcement action, if applicable). This section should also indicate who the action was coordinated with, i.e., OE, DEDO, or the Commission;

6. Either:
 - (a) A description of the response that is necessary from the licensee (if the region concludes that a response is necessary), including any area that deserves special emphasis; or
 - (b) A conclusion that a licensee response is not necessary (if the region concludes that a response is not necessary), including a provision that the licensee respond if its understanding of the corrective action is different;
7. A statement that the NRC will determine, based on the licensee's NOV response, corrective actions, and results of future inspections, whether further enforcement action is necessary:
8. A statement that the letter and the licensee's response will be made available to the Public; and
9. Any additional background information that supports the escalated enforcement action that was not previously submitted to support the panel, e.g., LER, TS, FSAR.

4.4.2 Escalated NOV Coordination and Review

- a. All escalated NOVs must be coordinated with OE and headquarters prior to issuance.
- b. If a proposed enforcement action is required to be submitted to headquarters for formal review and approval prior to issuance, it should be electronically mailed to:
 - OE ("OEMAIL")
 - The OE Enforcement Specialist
 - The Assistant General Counsel for Materials Litigation and Enforcement, and
 - The applicable program office Enforcement Coordinator
- c. Draft Commission papers should also be electronically mailed to the addressees listed above, as required.
- d. Notwithstanding the stated steps and timeliness goals for the coordination and review process, it is recognized that additional steps and/or review time may be necessary for unusually complex cases.

 For the purposes of this Manual, “**coordination**” means either that:

- The action needs to be submitted to headquarters for actual enforcement action package review; or
- The enforcement strategy for the action needs to be agreed upon (usually via a panel or caucus). The Strategy Form will document the level of OE review.

1. All escalated NOV's with Severity Level I, II, and III violations and all NOV's associated with red, yellow, or white SDP findings must be submitted to headquarters for enforcement action package review and approval prior to issuance.
 2. Unless OE requests, OGC will not normally provide comments for an escalated action issued without a civil penalty or order.
 3. The applicable program office should review the proposed action with a focus on ensuring that the technical accuracy of the violations and the significance of the violations with respect to safety and risk characterizations has been properly evaluated from an overall agency perspective.

✓ OGC review and statement of no legal objection(NLO) is required on enforcement actions included in Commission papers (e.g., actions including Severity Level I violations).
 4. Comments should be provided (verbally, electronically, or in writing) to OE and "OEMAIL" within 10 working days.
 - (a) Comments are normally provided through the program office Enforcement Coordinators.
 - (b) OE will consider timely program office comments and OGC comments, if proposed, and revise the enforcement action, as appropriate.
 - (c) The OE Enforcement Specialist will notify the applicable program office Enforcement Coordinator when substantive program office comments are not going to be incorporated into the final proposed enforcement action.
 5. OE will forward the revised enforcement package to the region indicating where the action was revised (normally through the use of comparative text) and explaining any significant changes.
 6. The region should review the revised action and, if possible, provide concurrence on headquarters' changes by the next day.
 7. OE will either:
 - (a) Approve the action (for Severity Level II materials actions); or as appropriate,
 - (b) Forward the OE-approved enforcement package to the DEDO for review and approval and will advise the DEDO of any significant differences among the region, the program office, and OGC.
 - e. Violations that involved interaction with OE and do not require a formal headquarters review and approval prior to issuance should be coordinated as follows:
-

1. Subsequent to a panel or caucus, or after additional discussions following a licensee's response to an inspection report where no conference has been conducted:
 - (a) OE will amend (as warranted) the Strategy Form to reflect the enforcement strategy that was agreed upon during the discussions and send it to the region and program office.
 - (b) The Strategy Form will indicate OE's concurrence with the enforcement strategy (provided that the region agrees with the summary).

✓ If there are additional discussions with the Regional Administrator and the Director, OE, the Strategy Form may need to be amended to represent the agreed upon strategy.
 - (c) If there are disagreements on the overall enforcement strategy, OE may request that the region submit the entire action (including the transmittal letter) to OE for formal review and approval prior to issuance.
2. Regional Counsel's review and statement of no legal objection is required prior to issuance by the region. If Regional Counsel is not available to review the case and there will be a significant delay due to the Regional Counsel's unavailability, then the region should submit the action to headquarters for OE review.
3. The region should send OE the complete escalated enforcement package after it has issued the action by including OEWEB/OEMail and the Enforcement Specialist on distribution.

4.4.3 Licensee Notification & Distribution of Escalated NOV's

- a. Licensee notification, mailing, and distribution should be made according to the following guidelines:
- b. In most cases, Escalated NOV's are mailed to licensees and States by regular mail. NRC distribution should be made according to the distribution lists in Appendix D and regional procedures.
- c. Copies of escalated NOV's issued by the program offices should be sent to OE as well as to the appropriate regional office.
- d. For all escalated enforcement actions involving medical licensees, the distribution list should include the Chairman, Board of Trustees.

✉ Escalated NOV's should be e-mailed to "OEWEB" when they are put in ADAMS to ensure that they are posted to the Enforcement Web site in a timely manner. The e-mail should include a statement such as, "The licensee has received a copy of the enforcement action."

1. The Board of Trustees frequently has oversight responsibility for the legal title, management of funds, and direction of policy for the medical licensee.
2. This distribution effort will:
 - (a) Ensure that escalated enforcement actions and their potential implications are raised to the highest level of authority;
 - (b) Deter future violations; and
 - (c) Promote the health and safety of the public, including employees' health and safety.
- e. In order to provide members of the public referenced information as soon as possible, when a press release is involved, the staff should release any escalated enforcement action to the public via ADAMS and the **Enforcement** Web site as soon as possible after it has notified the recipient of the enforcement action by e-mail or facsimile. **In all cases, the recipient(s) should receive the action before the press release is issued and before it is publically available.**

4.4.4 Licensee Response to Escalated NOVs

- a. If the region concludes that a licensee response is necessary, the provisions of 10 CFR 2.201 require that a licensee submit a written response to an NOV within 20 days of the date of the NOV or other specified time frame; however, normally 30 days should be used.
- b. If a licensee does not respond to an NOV within the allotted time and the region has made several unsuccessful attempts to contact the licensee, the region should contact OE (no later than 60 days from the date of the issuance of the NOV) and consideration will be given to whether additional enforcement action is warranted.
- c. Licensees may be granted response extensions where good cause is shown.
 1. The region may grant extensions of up to 30 days without OE approval.
 2. OE should be promptly notified of any extensions the region grants.
 3. OE approval is required for extensions beyond 30 days.
 - (a) Generally, verbal requests for extensions should be promptly followed up with written confirmation of the length of the extension and the date a reply is due.
 - (b) The confirmation may either be prepared by the NRC or the licensee, a copy of which should be sent to OE and the region.
 4. OE is responsible for notifying the Office of the Secretary when an enforcement hearing extension extending beyond 30 days is approved.

- d. A Licensee's response to an escalated NOV may either:
1. **Accept that the violation occurred as stated in the NOV.** In this case, the region should:
 - (a) Review the licensee's response for the adequacy of the corrective action, including whether the licensee has properly identified the root causes;

☛ Licensee denials include disputes involving NRC requirements, facts of the case, application of the Enforcement Policy, and severity levels.
 - (b) Send an acknowledgment letter usually within 30 days after receipt of the licensee's response to the same person and address as the escalated NOV.
 2. **Contest the staff's facts and/or conclusions regarding the escalated NOV.** In this case, the region should:
 - (a) Respond within 30 days after receipt of the licensee's response to the same person and address as the escalated NOV, addressing the licensee's points of contention and the acceptability of its corrective action.

☛ If the licensee disputes the SDP characterization of an inspection finding, the region should notify OE. While the dispute may not change the violation, it may affect how the violation should be dispositioned. In other words, if a licensee successfully argues that a white SDP finding should be green, the associated violation would likely be dispositioned as an NCV, instead of being considered escalated action. In this case, the subject line in the response to the licensee should include, "WITHDRAWAL OF ESCALATED ENFORCEMENT ACTION." OE should be notified in these cases and will take responsibility for removing any action from the **Enforcement** Web site.
 - (b) Within 21 days of the date of the licensee's denial, the region should prepare a response to the license and submit it for approval to OE, "OEMAIL," and the OE Enforcement Specialist handling the case.
 - (1) If the licensee denies the violation based on additional information not previously disclosed, the region should prepare a more detailed response, as appropriate.
 - (2) Any errors identified in the enforcement action must be addressed in the region's response.

3. **Disagree with the significance of the violation.** In this case, the region should:
 - (a) Follow the process described above when the licensee disagrees with the specific NRC guidance (i.e., Manual, Enforcement Policy, or MC 0612) that supports the significance of the violation.
 - (b) When the licensee disagrees with the significance of the violation but does not provide justification for its position, send an acknowledgment stating that the NRC reviewed the licensee's response and concluded that the licensee did not provide an adequate basis to reclassify the violation; therefore, the NRC maintains that the violation occurred as stated.
4. The subject line in the response to the licensee's denial should appropriately describe the agency's response as follows:
 - (a) If the NRC maintains that the NOV remains valid, the subject line should read, "RESPONSE TO DISPUTED NOTICE OF VIOLATION."
 - (b) If the region concludes that a second, revised NOV should be issued, the subject line should read, "REVISED NOTICE OF VIOLATION."
 - (c) If the region concludes that the violation should be withdrawn, the subject line should read, "WITHDRAWAL OF NOTICE OF VIOLATION."

4.5 Notice of Violation and Proposed Imposition of Civil Penalty (NOV/CP)

- a. Civil penalties are addressed in the Enforcement Policy.
- b. The procedures for issuing civil penalties are set forth in [10 CFR 2.205](#) .
- c. Civil penalties:

1. Are normally proposed for Severity Level I and II violations;
2. Are normally considered for Severity Level III violations;
3. May be proposed for knowing and conscious violations of the reporting requirements of section 206 of the Energy Reorganization Act; and
4. Are considered for violations associated with red, yellow or white SDP findings that involve actual consequences.

☛ Section 234 of the Atomic Energy Act (AEA) of 1954, as amended, authorizes the NRC to impose civil penalties not to exceed \$100,000 per violation, per day; however, that amount is periodically adjusted by the Debt Collection Improvement Act of 1996 and is currently \$130,000.

- d. Civil penalty actions are normally issued subsequent to conferences or after a licensee has had an opportunity to respond (e.g., in a PEC or in writing) to the apparent violations contained in an inspection report.
- e. The purpose of a civil penalty is not retributive, but remedial, and should:
 - 1. Encourage licensees to take effective and lasting corrective actions to avoid future problems by being in compliance; and
 - 2. Create a deterrent that will prevent future violations, both for the individual licensee and for other, similar licensees.
- f. When issuing a civil penalty, the following guidelines should be considered:
 - 1. Separate civil penalties should normally be assessed for separate violations with different root causes.
 - 2. Separate violations can be grouped as one violation in which case the cited violations should include both "requirement paragraphs" followed by one "contrary to" paragraph that addresses the common root cause and notes the resulting consequence.
 - 3. A single civil penalty should normally be assessed for violations that can be grouped into one problem when they are closely related, such as cause and affect type violations, e.g., it would be appropriate to view the failure to perform adequate testing that results in a piece of inoperable equipment as one problem, warranting consideration of one civil penalty.
 - 4. Notwithstanding a common root cause, separate civil penalties may be assessed for several violations that occurred over time, provided that each violation is addressed in its own citation (i.e., "contrary to" paragraph).
 - 5. Civil penalties may be issued to individual directors or responsible officers of a non-licensee vendor organization who knowingly and consciously fail to notify the NRC in accordance with 10 CFR Part 21. Section 206 of the Energy Reorganization Act (ERA) authorizes the NRC to impose civil penalties for knowing and conscious failures to provide certain safety information to the NRC.
 - 6. Section 234 of the AEA gives the NRC the authority to impose civil penalties on "any person," including licensee employees. However, pursuant to the Enforcement Policy, except as noted above, the NRC will not normally impose a civil penalty on an individual.

4.5.1 Preparing an NOV/CP Action

- a. The responsible office should prepare NOVs with civil by using the applicable standard format in Appendix B and the applicable standard citations in Appendix C.

- b. The NOV should be dated the same date as the cover letter transmitting the enforcement action.
- c. The NOV should include the following elements:
1. A concise, clear statement of the requirement or requirements that were violated, appropriately referenced, paraphrased, or quoted (legal citation for the violation).
 2. A brief statement (usually no more than a few sentences) of the circumstances of the violation, including the date(s) of the violation and the facts necessary and sufficient to demonstrate that the requirement was not met ("contrary to" paragraph).

✓ The NOV should be dated the same date as the cover letter transmitting the enforcement action.

 - (a) To demonstrate noncompliance, the language of the "contrary to" statement should parallel the applicable language of the requirement.
 - (b) Each violation, including a violation with multiple examples, contains a single "contrary to" statement.
 3. As a general rule, multiple examples of the same violation during the period covered by an inspection should be included in one citation.
 - (a) The "contrary to" paragraph should generally state the violation and then state: "...as evidenced by the following examples:" followed by the examples delineated as 1, 2, 3, etc.
 - (b) When the examples of a particular violation are numerous, sufficient examples should be cited to convey the scope of the violation and to provide a basis for assessing the effectiveness of the licensee's corrective actions. Normally three to five examples should be adequate.
 4. The severity level proposed for the violation or the severity level of the problem when several violations have been grouped.
 5. The applicable supplement of the Enforcement Policy under which the violation is categorized.
 6. The amount of the civil penalty proposed.
 7. The EA number should be included for each violation or problem when there is more than one escalated issue in the action.
 8. A statement requesting the licensee's response, to include:

- (a) Admission or denial of the alleged violation;
 - (b) The reason for the violation if admitted, and if denied, the reasons why;
 - (c) The corrective steps that have been taken and the results achieved;
 - (d) The corrective steps that will be taken to avoid further violations; and
 - (e) The date when full compliance will be achieved.
9. Instructions to the licensee for payment of the civil penalty or for protesting the civil penalty.
- b. Cover letters that transmits escalated NOV's with civil penalties to licensees should be prepared by the region using the appropriate form in Appendix B.
1. The letter should effectively and succinctly communicate the NRC's perspectives on the violations and the need for corrective action.
 2. In addition to an EA number, cover letters should include a Nuclear Materials Events Database (NMED) number, if applicable.
 3. If possible, the letter should normally be no longer than two pages in length for each violation and should include the following elements:
 - A summary of the purpose of the inspection
 - If and how the issue was reported, e.g., 50.72, LER etc.
 - When the inspection report(s) related to this action were issued
 4. A discussion of whether a conference was conducted, a choice letter was issued, or a choice call was made, as applicable.
 5. A conclusion that a violation(s) occurred and a very brief summary of the event or circumstances that resulted in the violation. The summary:
 - (a) Should not be as detailed as the discussion in the inspection report; however,
 - (b) It should be sufficiently detailed to permit licensee management and others who may review the action to understand the safety significance of the violations.

✓ To avoid the release of predecisional information, the top and bottom of all pages of documents included in escalated enforcement packages should be marked "**Official Use Only - Predecisional Enforcement Information.**" In addition, enforcement packages including safeguards information should be clearly marked: "Safeguards Information - Handle in Accordance With 10 CFR 73.21." Internal staff reviews and comments should not be made available to the Public (i.e., should not be publicly available in ADAMS (PARS)).

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- (c) A concise discussion of the safety significance of the violation in terms of whether it is based on the actual safety consequence, potential safety consequence, potential for impacting the NRC's ability to perform its regulatory function, or it was willful and how it relates to severity level categorization.
- (d) A statement of the base civil penalty amount for the violation or problem and a discussion addressing the applicable decisional points in the civil penalty assessment process, i.e., (1) whether the licensee has had any escalated actions for the site during the past two years or two inspections (include specific reference to any prior escalated action), (2) whether credit was given for identification (address only if the answer to (1) is no), and (3) whether credit was given for corrective action (include a brief description of corrective actions). It should also include an additional explanation if discretion was exercised, including a reference to the particular section of the Enforcement Policy.
- (e) A conclusion of why a civil penalty is being proposed. The conclusion should:
- (1) State the regulatory emphasis of the case, e.g., the importance of "system operability," "procedural compliance," "attention to detail," "accurate and complete information," "control of licensed material," compliance with technical specifications," "compliance with dose limits," etc;
 - (2) Address the licensee's shortcomings based on the civil penalty assessment process that resulted in the civil penalty, i.e., emphasize the importance of prompt identification and comprehensive correction of violations if the licensee did not get credit for these factors;
 - (3) Recognize previous escalated enforcement actions, if applicable;
 - (4) Indicate who the action was coordinated with, i.e., OE, DEDO, or the Commission;
 - (5) Indicate, as appropriate, additional concerns the NRC may have. However, care should be exercised to keep the correspondence focused on the overall regulatory concern; and
 - (6) Discuss any violations included in the enforcement action that were not assessed a civil penalty.
- (f) A description of the response that is necessary from the licensee which should be expanded if a particular response is desired.
- (g) A statement that the NRC will determine, based on the licensee's NOV/civil penalty response, corrective actions, and results of future inspections, whether further enforcement action is necessary.
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- (h) A statement that the letter and the licensee's response will be made available to the Public.
- (i) Any additional background information that supports the escalated enforcement action that was not previously submitted to support the panel, e.g., LER, TS, FSAR.

4.5.2 NOV/CP Coordination and Review

- a. All NOV/CP actions must be coordinated with OE and headquarters prior to issuance.
- b. Prior to issuance, proposed enforcement actions should be electronically mailed to headquarters for formal review and approval to:
 - OE ("OEMAIL")
 - The OE Enforcement Specialist
 - The Assistant General Counsel for Materials Litigation and Enforcement
 - The applicable program office Enforcement Coordinator
- c. Draft Commission papers should also be electronically mailed to the addressees listed above, as required.
- d. Notwithstanding the stated steps and timeliness goals for the coordination and review process, it is recognized that additional steps and/or review time may be necessary for unusually complex cases.
- e. All civil penalty actions including Severity Level I, II, and III violations are sent to headquarters for formal review and approval prior to issuance.
 - 1. OGC will review the proposed enforcement package and provide comments to OE within 10 working days of receipt of the package. OGC advises that acceptance of these comments does not necessarily constitute legal concurrence (or statement of no legal objection).

✓ OGC review and statement of no legal objection is required on enforcement actions included in Commission papers (e.g., actions including Severity Level I violations).
 - 2. The applicable program office should review the proposed action with a focus on ensuring that the technical accuracy of the violations and the significance of the violations with respect to safety and risk characterizations has been properly evaluated from an overall agency perspective.
 - 3. Comments should be provided (verbally, electronically, or in writing) to OE within 10 working days.
 - (a) Comments are normally provided through the program office Enforcement Coordinators.

- (b) OE will consider timely OGC and program office comments and revise the enforcement action, as appropriate.
 - (c) The OE Enforcement Specialist will notify the NRR, NMSS, or NSIR Enforcement Coordinator when substantive program office comments are not going to be incorporated into the final proposed enforcement action.
4. OE will forward the revised enforcement package to the region indicating where the action was revised (normally through the use of comparative text) and explaining any significant changes.
 5. The region should review the revised action and, if possible, provide concurrence on headquarters' changes by the next day.
 6. As appropriate, OE will forward the OE-approved enforcement package to the DEDO for review and approval and will advise the DEDO of any significant differences among the region, the program office, and OGC.
 7. The region should send OE the complete escalated enforcement package after it has issued the action by including OEWEB/OEMail and the Enforcement Specialist on distribution.

4.5.3 Licensee Notification & Distribution of NOV/CPs

- a. Licensee notification, mailing, and distribution should be made according to the following guidelines:
 1. In most cases, the region will notify the licensee by telephone of an enforcement action involving a civil monetary penalty.
 - (a) In certain cases (determined on a case-by-case basis), headquarters personnel will provide this notification.
 - (b) In all cases, the licensee will be notified of the proposed civil penalty before the information is made public.
 2. Licensees are to be provided a written copy of escalated enforcement actions as expeditiously as possible.
 - (a) Electronic transmission of escalated enforcement actions should be used to provide a written copy to licensees having facsimile equipment.

✓ Escalated NOVs should NOT be made publically available in ADAMS until confirmation that the licensee has received a copy of the enforcement action (i.e., e-mail, facsimile, courier). For individual actions, contacting the individual is sometimes problematic. In such cases, every reasonable attempt should be made to contact the individual before the action is made publicly available in ADAMS.

- (b) Alternatively, licensees in close geographic proximity to regional offices may choose to have a written copy picked up by courier from the regional office.
- (c) Escalated enforcement packages are to be mailed by either Certified Mail (Return Receipt Requested) or Express Mail. If facsimile equipment is not available, escalated enforcement packages are to be mailed by Express Mail.
3. The office in which the package is signed is responsible for its distribution.
- (a) Distribution lists for NRC addressees are in Appendix D.
- (b) A copy should be sent to the appropriate State. (The region's State Liaison Officer will normally handle this for program office cases, provided the Enforcement Specialist notifies the Regional Enforcement Coordinator.)
4. For all escalated enforcement actions involving medical licensees, the distribution list should include the Chairman and Board of Trustees.
- b. In order to provide members of the public referenced information as soon as possible, when a press release is involved, the staff should release any escalated enforcement action to the public via ADAMS and the Enforcement Web site as soon as possible after it has notified the recipient of the enforcement action by e-mail or facsimile.

✉ Escalated NOV's should be e-mailed to "OEWEB" when they are put in ADAMS to ensure that they are posted to the Enforcement Web site in a timely manner. The e-mail should include a statement such as, "The licensee has received a copy of the enforcement action."

✓ In all cases, the recipient(s) should receive the action before the press release is issued and before it is publically available. For individual actions, contacting the individual is sometimes problematic. In such cases, every reasonable attempt should be made to contact the individual before the press release is issued and the action becomes publicly available.

4.5.4 Licensee Response to NOV/CPs

- a. The provisions of 10 CFR 2.201 require that a licensee submit a written response addressing the violations included within a civil penalty action within 20 days of the date of the civil penalty action or other specified time frame; however, normally 30 days should be used.
- b. If a licensee does not respond to a civil penalty action within the allotted time and the region has made several unsuccessful attempts to contact the licensee, the region should contact OE (no later than 60 days from the date of the issuance of the action) and consideration will be given to whether additional enforcement action is warranted, i.e., the case should be

referred to the Attorney General, an order imposing the civil penalty should be issued, or whether some other enforcement action is warranted.

- c. The region may grant extensions of up to 30 days without OE approval.
 1. OE should be promptly notified of any extensions the region grants.
 2. OE approval is required for extensions beyond 30 days.
 3. Generally, verbal requests for extensions should be promptly followed up with written confirmation of the length of the extension and the date a reply is due. The confirmation may either be prepared by the NRC or the licensee. A copy of this followup correspondence is to be sent to OE and the region.
- d. As discussed below, licensees may:
 1. Admit the violation and pay the civil penalty;
 2. Deny the violation, contest the staff's facts or conclusions, or request mitigation of the civil penalty and pay the civil penalty; or
 3. Deny the violation, contest the staff's facts or conclusions, or request mitigation of the civil penalty and not pay the civil penalty.
- f. If the licensee **admits that the violation occurred** as stated in the NOV **and pays the civil penalty**, the regional office is to review the licensee's corrective action. The region should notify OE, usually within two weeks of receiving the licensee's response, of the acceptability of the licensee's response.
 1. Once OE has been notified by the region of the acceptability of the licensee's response, OE will send the licensee a letter acknowledging payment of the civil penalty and stating that the corrective actions described in the licensee's response will be examined during future inspections. This acknowledgment should be sent to the licensee within one week of the region's notification.
 2. If the region requires additional information from the licensee:
 - (a) The region should notify OE; and
 - (b) OE will send a letter acknowledging payment of the civil penalty and directing the licensee to provide the required information to the region.
 3. In either case, after OE sends an acknowledgment letter, OE will normally close out the associated EA number, thereby formally closing the case.

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- g. If the licensee **denies the violation**, contests the staff's facts or conclusions, or requests mitigation of the civil penalty, **but pays the civil penalty**, the region is to review the licensee's points of contention.
1. If the licensee presents additional information not previously disclosed:
 - (a) Careful consideration should be given to the appropriateness of the original proposed action.
 - (b) The region is to prepare an evaluation of the licensee's response and submit it to OE for possible inclusion in the acknowledgment letter sent by the Director, OE.
 2. If the licensee's response does not contain new information, then the region will:
 - (a) Prepare and submit to OE a brief response addressing only those issues that are significant and appropriate along with an assessment of the licensee's corrective action.
 - (b) OE will coordinate with the region and issue the NRC's response letter.
 3. Even if the licensee's response does not present new information, an error identified in the enforcement action must be corrected.
 4. Licensee responses that contest enforcement actions but pay civil penalties should usually be acknowledged within 45 days.
 5. If the licensee has paid a monetary penalty and then, based on the above review of the licensee's response, it appears that the penalty was **clearly** paid in error, the overpayment should be promptly returned to the licensee.
 - (a) OE will arrange to have a check issued from the Controller's Office.
 - (b) After it is determined that the Treasury has issued a check, OE will send a letter to the licensee explaining the modification to the civil penalty.
- h. If the licensee **denies the violation**, contests the staff's facts or conclusions, or requests mitigation of the civil penalty, **and does not pay the civil penalty**, the regional office should:
1. Review the licensee's response;
 2. Decide whether the civil penalty should be imposed, partially mitigated, or withdrawn; and
 3. Prepare a written evaluation of the licensee's response.
 - (a) The evaluation should:
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- (1) Be Submitted to OE within 45 days;
 - (2) Address the licensee's points of contention; and
- (b) The evaluation should include:
- (1) A restatement of each disputed violation;
 - (2) A summary of the licensee's position concerning each disputed violation;
 - (3) The NRC's evaluation of the licensee's position; and
 - (4) The NRC's conclusion.
4. If the region recommends that the civil penalty should be imposed, an Order Imposing Civil Monetary Penalty should be prepared with the staff's evaluation included as an appendix to the order.
 5. If the region recommends that the civil penalty should be partially mitigated, an Order Imposing Civil Monetary Penalty should be prepared to reflect partial mitigation with the staff's evaluation included as an appendix to the order.
 6. If the region recommends that the civil penalty should be withdrawn, the region should prepare a cover letter, for OE issuance, to the licensee with the staff's evaluation as an appendix to the letter.

4.5.5 NOV and NOV/CP Coordination and Review Output Measures

- a. Regional and OE (headquarters) timeliness on all escalated enforcement cases will be reported on a periodic basis to the Regional Administrators and Program Office Directors.
- b. The current timeliness output measures recognize that cases which include an OI investigation require additional time in order to review the OE report prior to determining the appropriate enforcement outcome.
 1. **Cases that do not include an OI investigation:**
 - 100% completed within 180 calendar days, and

Start Date: The measuring period starts on the latest of the following dates: (1) inspection exit date, (2) the date the results of an agency investigation are forwarded to the staff, (3) the date that the Department of Justice (DOJ) says NRC may proceed, for cases referred to the DOJ, or (4) the date of the Department of Labor decision that is the basis for the action. The inspection exit date will be defined by the region or office performing the inspection and may be the date of a telephone re-exit. For investigation cases, the start date will typically not be the a re-exit date. However, on rare occasions, when significant additional inspection effort is needed after issuance of the investigation results are forwarded to the staff, the re-exit date will be used as the start date.

- 100% will average 120 calendar days, reported by region and as an agency on a rolling four quarter basis.

2. Cases that include an OI investigation:

- 100% completed within 360 days of NRC processing time, and
- 100% will average 180 days of NRC processing time, reported by region and as an agency on a rolling four quarter basis.

Processing Time: NRC processing time is defined as that time from the date the case is opened to the issuance of an enforcement action or other appropriate disposition less: (1) anytime the NRC could not act due to the case residing with DOL, DOJ, other government entity, where additional OI field work is needed, or where the licensee requests a lengthy deferment, and (2) anytime the NRC could not act due to processing FOIA requests.

c. Enforcement Action Timeliness

Goals for processing escalated NOV's are based on the agency's enforcement action output measures.

1. Cases that do not include an OI investigation:

- Cases issued after OE consultation (usually via a panel or caucus) should be issued within 120 calendar days from the start date.
- Cases required to be submitted to headquarters prior to issuance should be submitted to headquarters within 90 calendar days from the start date.

2. Cases that include an OI investigation:

- Cases issued after OE consultation (usually via a panel or caucus) should be issued within 180 days of NRC processing time.
- Cases required to be submitted to headquarters prior to issuance should be submitted to headquarters within 150 days of NRC processing time.

4.6 Press Releases for NOV's and NOV/CP's

- Regional enforcement personnel will inform the regional Public Affairs Officer (RPAO) at least 72 hours prior to the issuance of an action.
- In the event that the RPAO decides to issue a press release, the RPAO will provide a draft press release to the regional staff for concurrence.
 - OE may review press releases in the more significant cases.
 - After the enforcement action has been signed, the RPAO will receive verification that the licensee has been notified of the action and has received a copy of the enforcement action.

- c. If the enforcement action has not been posted on the Enforcement Web site when the press release issued, the press release should state that the action will be posted on the [Enforcement Web page](#).
- d. The regional Enforcement Coordinator should consider the following when reviewing press releases:
 1. The severity level categorization;
 2. Whether the violation reflects an actual or a potential consequence;
 3. Whether the violation impacted the NRC's ability to perform its regulatory function;
 4. Whether the violation was willful; and
 5. Whether the licensee reported the violation or identified it.
- e. Press releases on the Web typically provide a link to the enforcement action on the Enforcement Web site.

4.7 Order Imposing Civil Monetary Penalty (Imposition Order)

- a. The procedures for issuing orders imposing civil penalties are set forth in [10 CFR 2.205](#) and the Enforcement Policy.
- b. The NRC issues an Order Imposing Civil Monetary Penalty when a licensee refuses to pay a civil penalty unless a basis exists for withdrawal of the proposed penalty.
- c. Draft Impositions, with the accompanying evaluation of the licensee's response and draft transmittal letter to the licensee, are submitted to OE within approximately 45 days of receipt of the licensee's response.

4.7.1 Preparing an Imposition Order Action

- a. The responsible office should prepare the imposition package, including the following elements as discussed below:
 1. An Order Imposing Civil Monetary Penalty should be prepared by using the applicable standard format in Appendix B. The Order Imposing Civil Monetary Penalty should be sent to the same person and address as the original proposed enforcement action. The order should include the following sections:
 - (a) The first section identifies the licensee, the license, the type of facility and location, and the date of issuance of the license.

- (b) The second section briefly describes the violation(s), when the Notice of Violation and Proposed Imposition of Civil Penalty was issued, and when responses were received from the licensee.
 - (c) The third section is the statement of the decision to impose the civil penalty.
 - (d) The fourth section is the statement that orders payment of the civil penalty.
 - (e) The fifth section states the licensee's opportunity to request a hearing.
2. A cover letter transmitting the order to the licensee should be prepared using the applicable form in Appendix B. The letter should:
- (a) Reference previous relevant correspondence between the licensee and the NRC, very briefly take into account any licensee rebuttal or reasons for mitigation or remission, impose the civil penalty.
 - (b) State that the order and its enclosures will be made available to the Public.
 - (c) Be more detailed if it is determined that an appendix will not be included (such as in certain discrimination cases).
3. An appendix may or may not be included as part of the package.
- (a) OE will coordinate with OGC, the region, and the program office to determine whether an appendix should be included.
 - (1) Certain cases (such as discrimination) may not require an appendix.
 - (2) If applicable, appendices should be prepared using the applicable form in Appendix B.
 - (b) The appendix should include:
 - (1) A restatement of each disputed violation;
 - (2) A summary of the licensee's response;
 - (3) An NRC evaluation of the response; and
 - (4) A conclusion.
 - (c) The appendix should discuss only violations that have been assessed a civil penalty.

- (1) If the licensee has contested any violations that were not assessed a civil penalty, those violations should be discussed in a separate document as an additional enclosure to the cover letter.
 - (2) In preparing the appendix it is important to understand that it puts the involved licensee, as well as other licensees, on notice regarding the NRC position. This permits other licensees to be aware of NRC concerns.
 - (3) The appendix may improve the NRC's litigative position by demonstrating careful consideration of the licensee's arguments.
4. The licensee's response to the proposed civil penalty action should be included in the enforcement package as background material if it has not already been provided in a panel.

4.7.2 Imposition Order Action Coordination and Review

- a. All Orders Imposing Civil Monetary Penalties are sent to headquarters for review and approval prior to issuance.
- b. The imposition package should be electronically mailed to:
 - OE ("OEMAIL")
 - The OE Enforcement Specialist
 - The Assistant General Counsel for Materials Litigation and Enforcement
 - The applicable program office Enforcement Coordinator
- c. Draft Commission papers, imposition packages and supporting background materials, including the licensee's response to the proposed civil penalty, should also be electronically mailed to the addressees listed above, as required.

☛ Impositions should be given priority treatment by both the region and headquarters offices.
- d. Notwithstanding the stated steps and timeliness goals for the coordination and review process, it is recognized that additional steps and/or review time may be necessary for unusually complex cases
- e. OGC review and statement of no legal objection is required on all Orders Imposing Civil Monetary Penalties. OGC will review the proposed order and provide comments to OE within 10 working days of receipt of the package.
- f. The applicable program office should review the proposed action with a focus on ensuring that the technical accuracy of the violations and the significance of the violations with respect to safety and risk characterizations has been properly evaluated from an overall agency perspective.

1. Comments should be provided (verbally, electronically, or in writing) to OE within 10 working days.
 2. Comments are normally provided through the program office Enforcement Coordinators.
 3. OE will consider OGC and program office comments and revise the enforcement action, as appropriate.
 4. The OE Enforcement Specialist will notify the NRR, NMSS, or NSIR Enforcement Coordinator when substantive program office comments are not going to be incorporated into the final proposed enforcement action.
 5. OE will forward the revised order to the region indicating where the action was revised (normally through the use of comparative text) and explaining any significant changes.
- g. The region should review the revised order and, if possible, provide concurrence on headquarter's changes by the next day.
- h. OE will obtain a statement of no legal objection from OGC and issue the action, if delegated to OE or, if warranted, will forward the OE-approved enforcement package to the DEDO for review and approval and will advise the DEDO of any significant differences among the region, the program office, and OGC.

4.7.3 Licensee Notification & Distribution of Imposition Orders

Licensee notification, mailing, and distribution of impositions should be made according to the following guidelines:

- a. In most cases, the region will notify the licensee by telephone of an Order Imposing Civil Monetary Penalty.
 1. In certain cases (determined on a case-by-case basis), headquarters personnel will provide this notification.
 2. In all cases, the licensee will be notified of the order before the information is made public.
- b. OE is to provide licensees with a copy of the order as expeditiously as possible. Electronic transmission should be used to provide a copy to licensees having facsimile equipment. Orders should be mailed by Express Mail.
- c. OE is responsible for distribution of the order.
 1. NRC distribution lists are in Appendix D.

 A copy of the action should be e-mailed to "OEWEB" to ensure that the action is posted to the Enforcement Web site in a timely manner.

2. A copy should also be sent to the appropriate State.
 3. For all escalated enforcement actions involving medical licensees, the distribution list should include the Chairman, Board of Trustees.
- ✓ In all cases, the recipient(s) should receive the action before any press release is issued and before it is publically available.
- d. The staff should release any escalated enforcement action to the public via ADAMS and the Enforcement Web site as soon as possible after it has notified the recipient of the enforcement action by e-mail or facsimile.
 - e. All Orders Imposing Civil Monetary Penalties are published in the *Federal Register*. OE is responsible for this action.

4.7.4 Press Releases for Imposition Orders

- a. Press releases are normally issued only for impositions where the amount of the civil penalty has been changed from the original civil penalty action.
 - b. Regional enforcement personnel will inform the Regional Public Affairs Officer (RPAO) when an imposition is about to be issued.
 1. For impositions involving a press release:
 - (a) The RPAO will provide the draft press release to the regional staff for concurrence.
 - (b) Upon request, OE may also review press releases in particularly significant cases.
 2. After the enforcement action has been signed, the RPAO will verify that the licensee has been notified of the action and has received a copy.
 - (a) Press releases on the Web typically provide a link to the enforcement action on the Enforcement Web site.
 - (b) If the licensee issues its own press release during the intervening period, the RPAO may proceed to issue an NRC press release.
- ✓ To avoid the release of predecisional information, the top and bottom of all pages of documents included in escalated enforcement packages should be marked "**Official Use Only - Predecisional Enforcement Information.**" In addition, enforcement packages including safeguards information should be clearly marked: "Safeguards Information - Handle in Accordance With 10 CFR 73.21." Internal staff reviews and comments should not be made available to the Public (i.e., should not be publicly available in ADAMS (PARS)).

- c. Press releases for impositions should indicate whether the originally proposed civil penalty is being imposed partially or in full.

4.7.5 Licensee Response to Imposition Order

- a. The provisions of 10 CFR 2.202 require that a licensee submit a written response to an order under oath or affirmation within 20 days of the date of the order or other specified time frame; however, normally 30 days should be used.
 1. A licensee may either:
 - (a) Pay the civil penalty; or
 - (b) Request a hearing.
- b. If a licensee does not respond to the order within the allotted time, the region should contact OE and the case will be referred to the Attorney General for collection.
- c. If a licensee requests a hearing, OE will provide the request to OGC to forward to the Office of the Secretary of the Commission.
- d. Where good cause is shown, the staff may consider granting a licensee an extension of time to request a hearing.
 1. A licensee's request for an extension must be made in writing to the Director, OE; and
 2. Include a statement of good cause for the extension.

4.8 Order Modifying, Suspending, or Revoking License

- a. The procedures for issuing orders are set forth in [10 CFR 2.202](#) and the Enforcement Policy.
- b. An **order** is a written NRC directive to:
 1. Modify, suspend, or revoke a license;
 2. Cease and desist from a given practice or activity; or
 3. Take such action as may be proper.

 The guidance included in this section is intended to primarily address orders based on compliance issues, i.e., orders that are issued based on the failure to comply with existing regulatory requirements. The program offices may issue safety orders that impose additional requirements beyond the existing regulations (e.g., 2002 security orders). In addition to program office guidance for these safety orders, the staff should follow the guidance included in this manual regarding the issuance of Enforcement Notifications (ENs), Web site postings, and the issuance of EA numbers.

- c. Orders may also be issued in lieu of, or in addition to civil penalties, as appropriate for Severity Level I, II, or III violations.
- d. Unless a separate response is warranted, an NOV need not be issued where an order is based on violations described in the order. The violations described in the order need not be categorized by severity level.
- e. The NRC may also issue orders to unlicensed persons, including vendors and contractors (and employees), when the NRC has identified deliberate misconduct that may cause a licensee to be in violation of an NRC requirement or where incomplete or inaccurate information is deliberately submitted or where the NRC loses its reasonable assurance that the licensee will meet NRC requirements with that person involved in licensed activities.
- f. **License Modification Orders** are issued when some change in licensee equipment, procedures, personnel, or management controls is necessary.
- g. **Suspension Orders** may apply to all or part of the licensed activity. Ordinarily, a licensed activity is not suspended (nor is a suspension prolonged) for failure to comply with requirements where such failure is not willful and adequate corrective action has been taken. Suspension Orders may be used to:
 1. Remove a threat to the public health and safety, common defense and security, or the environment;
 2. Stop facility construction; or
 3. Revoke the license when:
 - (a) The licensee has not responded adequately to other enforcement action;
 - (b) The licensee interferes with the conduct of an inspection or investigation;
 - (c) Any other reason for which license revocation is legally authorized exists.
- h. **Revocation Orders** may be used:
 1. When a licensee is unable or unwilling to comply with NRC requirements;
 2. When a licensee refuses to correct a violation;
 3. When a licensee does not respond to an NOV where a response was required;
 4. When a licensee refuses to pay an applicable fee under the Commission's regulations; or

Orders should be prepared within time-frames that are consistent with the safety and regulatory significance of the situations.

5. Any other reason for which revocation is authorized under Section 186 of the Atomic Energy Act (e.g., any condition which would warrant refusal of a license on an original application).
- i. **Cease and Desist Orders** may be used to stop an unauthorized activity that has continued after notification by NRC that the activity is unauthorized.

4.8.1 Immediately Effective Orders

- a. Orders may be effective after a licensee or individual has had an opportunity to request a hearing.
 1. In such cases, the order becomes effective on the day following the deadline for requesting a hearing, if the licensee does not request a hearing.
 2. If the licensee requests a hearing, the order becomes effective as determined in the hearing process.
- b. Orders can be made immediately effective without prior opportunity for a hearing whenever the NRC determines that the public health and safety or common defense and security interests so require, or when the order is responding to a violation involving willfulness.
 1. These orders must specify the basis for their immediate effectiveness.
 - (a) The discussion should support the finding that the Commission no longer has reasonable assurance that activities will be conducted without undue risk to the public's health and safety.
 - (b) Immediately effective orders should be expedited.
 - (c) Immediately effective orders should also be supported by a draft affidavit prepared by a person who can testify as to why the public health, safety, or interest requires an immediately effective order in this case.
- c. All orders are published in the *Federal Register*. OE is responsible for this action.
- d. If an immediately effective order is needed to eliminate an immediate hazard arising from a violation that also warrants a civil penalty, the order should be expedited, and the civil penalty issued promptly thereafter.

4.8.2 Preparing an Order Action

- a. The responsible office should prepare the civil penalty package, including the following elements as discussed below:
 1. The order should be prepared using the applicable standard format in Appendix B. Depending on the type of order, the order will include any of the following sections:

- (a) A section that identifies the licensee, the license, the type of facility and location, and the date of issuance of the license.
 - (b) A section that describes the relevant events, facts, violations, technical aspects or legal reasons that substantiate issuing the order.
 - (c) A section that provides the justification for issuing the order.
 - (d) For a confirmatory order, a section that confirms, by the order, a licensee's commitments to take certain actions.
 - (e) A section that orders modification, suspension, or revocation of the license.
 - (f) A section that states the licensee's obligation to respond to the order.
 - (g) A section that states the opportunity for a licensee or any other person adversely affected by the order to request a hearing.
2. A cover letter transmitting the order to the licensee should be prepared using the applicable format in Appendix B, customized to reflect the specific order.
 - (a) The letter should briefly state the basis for the order and describe any actions required or prohibited based on the order.
 - (b) The letter should also state that failure to comply with the provisions of the order may result in civil and criminal sanctions and that the letter and its enclosures will be made available to the Public.
 - (c) A contact should be provided. This is normally the Director, OE.
 3. For immediately effective orders, the originating office should provide, with the draft package, a draft affidavit to support the order's immediate effectiveness.
 4. Because [10 CFR 2.202\(c\)\(2\)\(i\)](#) requires the staff to respond to a motion to set aside immediate effectiveness within 5 days of receipt of the motion, the originating office must be prepared to make the knowledgeable personnel available to put the affidavit in final form (see applicable form in Appendix B).

4.8.3 Order Coordination and Review

- a. All orders are sent to headquarters for review and approval prior to issuance.
- b. The order package should be electronically mailed to:
 - OE ("OEMAIL")

✓ Immediately effective orders should be expedited. Delaying issuance undermines the basis for the necessity of an immediately effective order.

- The OE Enforcement Specialist
 - The Assistant General Counsel for Materials Litigation and Enforcement
 - The applicable program office Enforcement Coordinator
- c. Draft Commission papers, order packages and supporting background materials should be electronically mailed to the licensees listed above, as required.
- d. Notwithstanding the stated steps and timeliness goals for the coordination and review process, it is recognized that additional steps and/or review time may be necessary for unusually complex cases.
- e. Orders should be given priority treatment by both the region and headquarters offices.
- f. OGC review and statement of no legal objection is required on all orders. OGC will review the proposed order and provide comments to OE within 10 working days of receipt of the package.
- g. The applicable program office should review the proposed action with a focus on ensuring that the technical accuracy of the violations and the significance of the violations with respect to safety and risk characterizations has been properly evaluated from an overall agency perspective.
1. Comments should be provided (verbally, electronically, or in writing) to OE within 10 working days.
 2. Comments are normally provided through the program office Enforcement Coordinators.
 3. OE will consider OGC and program office comments and revise the enforcement action, as appropriate.
 4. The OE Enforcement Specialist will notify applicable program office Enforcement Coordinator when substantive program office comments are not going to be incorporated into the final proposed enforcement action.
- h. OE will forward the revised order to the region indicating where the action was revised (normally through the use of comparative text) and explaining any significant changes.
- i. The region should review the revised order and, if possible, provide concurrence on headquarters' changes by the next day.
- j. OE will obtain a statement of no legal objection or concurrence from OGC and issue the order if delegated or, if warranted, will forward the OE-approved enforcement package to the DEDO for review and approval and will advise the DEDO of any significant differences among the region, the program office, and OGC.
- k. For Confirmatory Orders, the consent of the recipient of the order is required.

1. OE will forward the draft order to the recipient with the text of the ordering portion of the proposed order and a cover letter requesting that the appropriate person sign and return the letter agreeing to the issuance of the order and the fact that the consent waives the right to request a hearing on the order.
2. The text of the order itself will recite the consent to the order.

4.8.4 Licensee Notification & Distribution of Orders

Licensee notification, mailing, and distribution should be made for orders according to the following guidelines:

- a. In most cases, the region will notify the licensee by telephone of the issuance of an order.
 1. In certain cases (determined on a case-by-case basis), headquarters personnel will provide this notification.
 2. In all cases, the licensee will be notified of the order before the information is made public.
- b. Licensees are to be provided a written copy of the order as expeditiously as possible.
 1. Electronic transmission should be used to provide a written copy to licensees having facsimile equipment.
 2. Orders should be mailed by Express Mail.
- c. OE is responsible for distribution of the order.
 1. Distribution lists for NRC addressees are in Appendix D.
 2. Orders involving individuals where they are restricted from licensed activities in general, should be sent to the Office of State Programs for distribution to all Agreement States.
 3. For all escalated enforcement actions involving medical licensees, the distribution list should include the Chairman, Board of Trustees.
- d. The staff should release any escalated enforcement action to the public via ADAMS and the Enforcement Web site as soon as possible after it has notified the recipient of the enforcement action by e-mail or facsimile. In all cases, the recipient(s) should receive the action before any press release is issued and before it is publically available.
- e. All orders are published in the *Federal Register*. OE is responsible for this action.

✉ A copy of the action should be e-mailed to "OEWEB" to ensure that the action is posted to the Enforcement Web site in a timely manner. The e-mail should include a statement such as, "The licensee has received a copy of this action," so that the Web staff will know that it can be posted.

4.8.5 Press Releases for Orders

- a. Press releases are generally issued for all orders other than impositions.
- b. Regional enforcement personnel will inform the Regional Public Affairs Officer (RPAO) when these actions are about to be issued.
 1. The RPAO will provide a press release to the regional staff for concurrence.
 2. OE may also review press releases in some particularly significant cases.
 3. After the enforcement action has been signed, the RPAO will verify that the licensee has been notified of the action and has received a copy.
 4. Press releases on the Web typically provide a link to the enforcement action on the Enforcement Web site.
 5. If the licensee issues its own press release during the intervening period, the RPAO may proceed to issue an NRC press release.

4.8.6 Licensee Responses to Orders

- a. The provisions of [10 CFR 2.202](#) require that a licensee submit a written response to an order under oath or affirmation within 20 days of the date of the order or other specified time frame.
- b. The licensee may:
 1. Consent to the order,
 2. Admit or deny each allegation and provide a basis as to why the order should not have been issued; and/or
 3. Request a hearing.
- c. If a licensee does not request a hearing by the deadline provided, the order becomes effective at that time (for orders not immediately effective at the time of issuance).
- d. Questions concerning the effectiveness and scope of a given order should be referred to OE.
- e. If the licensee has requested a hearing and subsequently calls the NRC to discuss the case, the call should be referred to OE.
 1. OE will ensure that the assigned OGC hearings attorney is present in any discussions.

2. If a licensee requests a hearing, OE will provide a copy to OGC to forward to the Office of the Secretary of the Commission.
- f. Where good cause is shown, the staff may consider granting a licensee an extension of time to request a hearing. The request for an extension must:
1. Be made in writing to the Director, OE; and
 2. Include a statement of good cause for the extension.

4.8.7 Relaxation of Orders

- a. An order provides that the Regional Administrator may relax or terminate conditions of the order.
1. The purpose of this provision is to avoid the need to issue another order should the order need to be relaxed.
 2. The Regional Administrator is named to ensure that the licensee works directly with the region concerning the order.
 3. The same offices that were involved in issuing the order are to be involved before relaxing or terminating a provision of the order.
 4. If the region finds it appropriate to relax or terminate an order, OE should be contacted and OE will obtain the views (as appropriate) of NRR, NMSS, NSIR, OGC, and the DEDO.
 5. In some orders, the Director, OE, is the designated official who can relax the order. In these cases, OE will obtain the views of the appropriate offices.
 6. In some cases, the decision is made to withdraw an order.
 1. Use of the term "withdraw" is appropriate when dropping all or part of an order.
 2. The term "rescind" should be used when it is concluded that because of a basic mistake of law or fact, the action should not have been issued at all.

If the Director of NRR or NMSS relaxes a program office security order, a copy of the correspondence to the licensee should be sent to "OEWEB" to ensure prompt posting in the security order document collection.

4.9 Demand for Information (DFI)

- a. The procedures for issuing Demands for Information (DFIs) are set forth in [10 CFR 2.204](#) and the Enforcement Policy.

- b. A **DFI** is a formal request made to a licensee or applicant to obtain information to determine whether the license should be granted, or if issued, whether it should be modified, suspended, or revoked, or other enforcement action taken.
 1. DFIs may be issued to unlicensed persons, including vendors and contractors (and employees), for the purpose of enabling the NRC to determine whether an order or other enforcement action should be issued.
 2. A DFI may be included within another escalated action, such as an order or proposed imposition of civil penalty.
 3. A DFI is a significant action. It should be used only when it is likely that an inadequate response will result in an order or other enforcement action.

4.9.1 Preparing a DFI Action

The responsible office should prepare the DFI package, including the following elements as discussed below:

- a. The DFI should be prepared using the applicable standard format in Appendix B. The Demand should include the following sections:
 1. A section that identifies the licensee, the license, the type of facility and location, and the date of issuance of the license.
 2. A section that describes the relevant events, facts, alleged violations, potentially hazardous conditions, technical aspects or legal reasons that provide the substantive basis for issuing the DFI.
 3. A section that requires specific information from the licensee by a certain date (determined on a case-by-case basis) to determine whether the license should be modified, suspended, or revoked.
- b. A cover letter transmitting the DFI to the licensee should be prepared using the applicable form in Appendix B, customized to reflect the DFI as the applicable enforcement action. The letter should:
 1. Briefly state the basis for the DFI;
 2. Describe the information requested;
 3. State that the failure to comply with the DFI provisions may result in enforcement action; and
 4. Note whether the DFI will be made available to the Public.

- c. As noted above, a DFI may also be incorporated into another action. In such cases, the DFI is normally included, in an abbreviated format, as part of the transmittal letter for the accompanying action, using language similar to the following:

“In addition, pursuant to Sections 161c, 161o, 182, and 186 of the Atomic Energy Act of 1954, as amended, 10 CFR 2.204 and 50.54(f), in order for the Commission to determine whether your license should be modified or other actions taken, you are required to submit to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, DC 20555, within 30 days of the date of this Demand for Information, in writing and under oath or affirmation, an explanation as to:

(1) why the NRC can have confidence that [request information specific to the circumstances of the case] . . . “

- d. Copies of the response to the DFI should be sent to:
1. The Associate General Counsel for Hearings, Enforcement & Administration at the same address; and
 2. The Regional Administrator, specifying the region and regional address.

4.9.2 DFI Coordination and Review

- a. All DFIs are assigned EA numbers and are sent to headquarters for review and approval prior to issuance.
- b. The DFI package should be electronically mailed to:
- OE ("OEMAIL")
 - The OE Enforcement Specialist
 - The Assistant General Counsel for Materials Litigation and Enforcement
 - The applicable program office Enforcement Coordinator
- c. Draft Commission papers, order packages and supporting background materials should be electronically mailed to the addressees listed above, as required.
- d. Notwithstanding the stated steps and timeliness goals for the coordination and review process, it is recognized that additional steps and/or review time may be necessary for unusually complex cases.
- ✓ Orders should be given priority treatment by both the region and headquarters offices.
- e. If requested, OGC will review the proposed DFI and provide comments to OE within 10 working days of receipt of the package.
- f. The applicable program office should review the proposed action with a focus on ensuring that the technical accuracy of the violations and the significance of the violations with

respect to safety and risk characterizations has been properly evaluated from an overall agency perspective.

1. Comments should be provided (verbally, electronically, or in writing) to OE within 10 working days.
 2. Comments are normally provided through the program office Enforcement Coordinators.
 3. OE will consider timely OGC and program office comments and revise the DFI, as appropriate.
 4. The OE Enforcement Specialist will notify the applicable program office Enforcement Coordinator when substantive program office comments are not going to be incorporated into the final proposed enforcement action.
 5. The OE Enforcement Specialist will notify the program office Project Manager when substantive program office comments are not going to be incorporated into the final proposed enforcement action.
- g. OE will forward the revised DFI to the region indicating where the action was revised (normally through the use of comparative text) and explaining any significant changes.
- h. The region should review the revised DFI and, if possible, provide concurrence on headquarters' changes by the next day.
- i. OE will attempt to resolve any differences among the region, the program office, and OGC.

4.9.3 Licensee Notification & Distribution of DFI

Licensee notification, mailing, and distribution for DFIs should be made according to the following guidelines:

- a. In most cases, the region will notify the licensee by telephone of the issuance of a DFI. However, in certain cases (determined on a case-by-case basis), headquarters personnel will provide this notification.
- b. Licensees are to be provided a written copy of the Demand as expeditiously as possible. Electronic transmission should be used to provide a written copy to licensees having facsimile equipment. Demands should be mailed by Express Mail.
- c. OE is responsible for distribution of the Demand (see the distribution lists for NRC addressees are in Appendix D).

4.9.4 Licensee Response to DFI

- a. The provisions of [10 CFR 2.204](#) require that a licensee submit a written response to a DFI under oath or affirmation within 20 days of the date of the DFI or other specified time frame (determined on a case-by-case basis).
- b. If a licensee does not respond to a DFI within the required time, the NRC will consider issuing an order to modify, suspend, or revoke the licensee or consider taking such other action as necessary to compel a response.
- c. After reviewing the licensee's response to the DFI, the NRC determines whether further action is necessary to ensure compliance with regulatory requirements.

4.10 Letters of Reprimand

- a. **Letters of Reprimand** (LORs) are letters addressed to an individual (licensed or unlicensed) subject to Commission jurisdiction identifying a significant deficiency in his or her performance of licensed activities. LORS should only be considered where an individual could be cited.

☞ If the staff decides that action should not be taken against an individual (for what ever reason) the staff should normally prepare a close-out letter rather than a LOR.

- b. Generally, using an LOR may be considered when:
 1. An individual violation has been established;
 2. The violation is not one of deliberate misconduct;
 3. The violation(s) is (are) not of 10 CFR Part 26 for use or abuse of drugs and/or alcohol; and
 4. The individual has proactively proposed or has already taken correction actions well beyond what would be required for minimum corrective actions.
- c. The NRC may determine that, because the individual has taken the significant corrective action(s) to address the documented performance deficiency, formal enforcement action such as an NOV against the individual is not warranted.
- d. An LOR serves as a vehicle for notifying the individual that his or her actions are unacceptable, and may be issued in conjunction with an enforcement action against the licensee. As such, they are expected to be used infrequently, and in lieu of issuing an NOV or other escalated enforcement action to the individual.

4.10.1 Preparing an LOR Action

- a. The responsible office should prepare the LOR package, including the following elements as discussed below:

- b. The LOR should be prepared using the applicable standard format in Appendix B.
1. The letter is not labeled as a "Letter of Reprimand" in the subject line.
 2. The LOR should, depending on the recipient and nature of the letter, include the following elements, as applicable:

- (a) Docket and license numbers.
- (b) A description of relevant events, facts, or circumstances that substantiate issuing the LOR. This description should reference relevant inspection reports, OI reports, previous correspondence, or predecisional enforcement conferences.
- (c) A discussion of enforcement action, if any, that was taken against the facility licensee. If an enforcement action was issued to the facility, a copy should be enclosed.
- (d) Notification of the NRC's authority to take action against individuals, e.g.,

✓ To avoid the release of predecisional information, all documents included in LOR packages should be marked "Proposed Enforcement Action: Not For Public Disclosure Without The Approval Of The Director, OE." In addition, LOR packages including safeguards information should be clearly marked: "Safeguards Information - Handle in Accordance With 10 CFR 73.21." Internal staff reviews and comments should not be made available to the Public (i.e., should not be publicly available in ADAMS (PARS)).

- "You should be aware that the NRC's regulations allow enforcement actions to be issued directly to unlicensed persons who through their deliberate misconduct, cause a licensee to be in violation of NRC requirements. Similarly, an order may be issued to such an individual preventing him or her from engaging in licensed activities at all NRC licensed facilities."
- (e) The basis for not issuing formal enforcement action against the individual.
 - (f) A statement notifying the individual that his or her actions are unacceptable and that if uncorrected or continued, could lead to formal NRC enforcement action.
 - (g) A statement that the individual is not required to respond to the letter. However, if the individual wants to respond, the response should be made to the originating office within 30 days of the date of the letter.
 - (h) If the recipient is licensed, a statement that the letter (and any enclosures), with the individual's home address deleted will be placed in the docket file for the license.

4.10.2 LOR Coordination and Review

- a. All LORs are assigned EA numbers (during review and approval) and are sent to headquarters for review and approval prior to issuance.
- b. The LOR package should be electronically mailed to:
- OE ("OEMAIL")
 - The OE Enforcement Specialist
 - The Assistant General Counsel for Materials Litigation and Enforcement
 - The applicable program office Enforcement Coordinator
- c. Draft Commission papers, order packages and supporting materials should be electronically mailed to the addressees listed above, as required.
- d. Notwithstanding the stated steps and timeliness goals for the coordination and review process, it is recognized that additional steps and/or review time may be necessary for unusually complex cases.
- e. Unless OE requests, OGC will not normally provide comments for LORs after the initial enforcement panel.
- f. The applicable program office should review the proposed action with a focus on ensuring that the technical accuracy of the violations and the significance of the violations with respect to safety and risk characterizations has been properly evaluated from an overall agency perspective.
1. Comments should be provided (verbally, electronically, or in writing) to the OE Enforcement Specialist within 10 working days.
 2. The program office Enforcement Coordinators normally provide comments.
 3. OE will consider timely program office comments (if applicable) and revise the LOR, as appropriate.
 4. The OE Enforcement Specialist will notify the program office Enforcement Coordinator when substantive program office comments are not going to be incorporated into the final proposed enforcement action.
- g. OE will forward the revised LOR to the region indicating where the action was revised (normally through the use of comparative text) and explaining any significant changes.
- h. The region should review the revised LOR and, if possible, provide concurrence on headquarters' changes by the next day.

✓ LORs should be given priority treatment by both the region and headquarters offices.

- i. OE will approve issuance of the action or, if warranted, will consult with the DEDO, as appropriate.
- j. OE will assign the action an IA number when it is ready to be issued.

4.10.3 Notification & Distribution of LORs

- a. The region is responsible for mailing and distributing LORs. LORs should be mailed by either Certified Mail (Return Receipt Requested) or Express Mail. OE should be on distribution for all LORs. In addition, the licensee should be shown on the "cc" on the LOR.
- b. LORs are not posted on the [Enforcement Web site](#) of significant actions.
 - 1. Because some LORs may be issued in conjunction with escalated enforcement actions, the following guidance should be followed to avoid posting LORs on the Web.
 - (a) The escalated enforcement action cover letter to the licensee should indicate that an LOR is being, or has been, issued in separate correspondence.
 - (b) The LOR should not be shown as an enclosure to the action to the licensee.
- c. The region must ensure that the copies of LORs that are made available to the Public do not include individuals' home addresses.

4.11 Settlement of Enforcement Proceedings and Actions

- a. The procedures for settlement of a proceeding to modify, suspend, or revoke a license or other action and compromise of a civil penalty are set forth in [10 CFR 2.203](#).
- b. For those cases where a hearing has been requested:
 - 1. Normally OGC has the lead;
 - 2. The staff is responsible for preparing a settlement agreement;
 - 3. The settlement agreement should retain the same EA number as the original proposed enforcement action and should be signed by the signatory official for the licensee and a hearings attorney for the NRC;
 - 4. The stipulation or compromise is subject to approval by the designated presiding officer, or if none has been designated, by the Chief Administrative Law Judge; and
 - 5. If approved, the Atomic Safety and Licensing Board Panel (ASLBP) will issue a decision or order settling and discontinuing the proceeding that will include the terms of the settlement or compromise.

- c. For those cases that do not involve a hearing, the staff (normally OE) is responsible for preparing a settlement agreement (see the sample standard format in Appendix B).
 - 1. The settlement agreement should retain the same EA number as the original proposed enforcement action and should be signed by the signatory official for the licensee and the Director, OE, for the NRC.
 - 2. The settlement is subject to approval by the Director, OE after consultation, as warranted, with the DEDO.
 - 3. If approved, the staff (normally OE) will prepare an order settling, modifying, or discontinuing the enforcement action that will include the terms of the settlement or compromise using the standard format in Appendix B.